

Valparaíso University

ValpoScholar

---

Evidence-Based Practice Project Reports

College of Nursing and Health Professions

---

5-2020

## What's All the Buzzy About? Using Cryotherapy and Vibration for Pain During Vaccinations in Children

Marta L. Byma

Follow this and additional works at: <https://scholar.valpo.edu/ebpr>



Part of the [Analytical, Diagnostic and Therapeutic Techniques and Equipment Commons](#), [Child Psychology Commons](#), [Family Medicine Commons](#), [Family Practice Nursing Commons](#), [Maternal, Child Health and Neonatal Nursing Commons](#), [Pediatric Nursing Commons](#), [Pediatrics Commons](#), and the [Primary Care Commons](#)

---

This Evidence-Based Project Report is brought to you for free and open access by the College of Nursing and Health Professions at ValpoScholar. It has been accepted for inclusion in Evidence-Based Practice Project Reports by an authorized administrator of ValpoScholar. For more information, please contact a ValpoScholar staff member at [scholar@valpo.edu](mailto:scholar@valpo.edu).



**WHAT'S ALL THE BUZZY ABOUT? USING CRYOTHERAPY AND VIBRATION FOR  
PAIN DURING VACCINATIONS IN CHILDREN**

by

**MARTA L. BYMA**

**EVIDENCE-BASED PRACTICE PROJECT REPORT**

Submitted to the College of Nursing and Health Professions

of Valparaiso University,

Valparaiso, Indiana

in partial fulfillment of the requirements

For the degree of

**DOCTOR OF NURSING PRACTICE**

2020

Copyright © 2020 by Marta L. Byma



**This work is licensed under a  
Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License.**

## **DEDICATION**

This project is dedicated to my wonderful family and friends. To my awesome husband; you have kept me going throughout this entire DNP program and I truly could not have done it without you. Thank you for pushing me to pursue my dreams and forcing me to keep going when I felt like giving up. Your patience and understanding with all the highs and lows of this program has allowed me to fully succeed towards a goal that I never thought was possible. Thank you for all the sacrifices that you have made over the last three years. To my wonderful parents, siblings, nieces, and nephews thank you for all of the love, support, and prayers throughout these past couple of years. I wouldn't be half the person I am today without being raised by such loving parents. Mom, thank you for letting me talk your ear off on the phone about all things nursing, and Dad, thanks for putting up with our "reports" that lasted far too long. To my husband's family, thank you for putting up with all of the family gatherings that were missed due to my busy schedule. Thank you for supporting me, praying for me, loving me, and making me feel like I have always belonged. Finally, thank you to my friends. To Suzy, David, Eric, and Kenzie, there is not a chance that I would have made it through this program without each of you. Thank you for making me laugh till I cry, for listening to my complaining, and for pushing me to be better. Guys, we did it!

## **ACKNOWLEDGMENTS**

I would like to begin by thanking my incredible project advisor, Dr. Christina Cavinder. Thank you for your patience, kindness, guidance, and expertise throughout this project. It has been a pleasure learning from her in both the classroom setting, as well as through her work as a neonatal nurse practitioner. I appreciate all the time and dedication that she has poured into me throughout the last three years, especially in the last year during the DNP project.

I would also like to thank my site facilitator and clinical staff that believed in the need for change and graciously accepted the use of the Buzzy® device into their practice. I wanted to also thank the practice site for kindly investing in the purchase of the Buzzy® device for my project. I greatly appreciated the staffs support throughout the project, the time that they invested in using the device, and the feedback received after the project was finished.

## TABLE OF CONTENTS

<b>Chapter</b>	<b>Page</b>
DEDICATION.....	iii
ACKNOWLEDGMENTS.....	iv
TABLE OF CONTENTS .....	v
LIST OF TABLES.....	vi
ABSTRACT.....	vii
CHAPTERS	
CHAPTER 1 – Introduction.....	1
CHAPTER 2 – EBP Model and Review of Literature .....	9
CHAPTER 3 – Implementation of Practice Change .....	36
CHAPTER 4 – Findings.....	45
CHAPTER 5 – Discussion.....	51
REFERENCES.....	63
AUTOBIOGRAPHICAL STATEMENT.....	67
ACRONYM LIST.....	68
APPENDICES	
APPENDIX A – CITI Program.....	69
APPENDIX B – Informed Consent Form.....	70
APPENDIX C – Goshen IRB Exempt Letter.....	72

## LIST OF TABLES

<b>Table</b>	<b>Page</b>
Table 2.1 Evidence Search Table.....	17
Table 2.2 Evidence Summary Table.....	26
Table 4.1 Demographic Characteristics.....	47

## ABSTRACT

Vaccinations are the most common painful needle procedure, with an estimated 12 billion injections given per year (CDC, 2019). The usual method for administration of vaccinations is through needle puncture, which is often painful. Children often report receiving a shot as one of the most feared and painful experiences (McMurtry et al., 2015). The purpose of this evidence-based practice (EBP) project was to improve patient experiences by decreasing the pain that is associated with vaccinations through the use of a nonpharmacological method for comfort via the Buzzy® device. After thorough analysis and synthesis of the literature, the Buzzy® device that incorporates cryotherapy and vibration was selected and used during vaccinations in children ages newborn to seven years of age. The Johns Hopkins Nursing Evidence Based Practice Model was selected as a guide for the EBP project development, planning, and implementation at an outpatient family practice office in Northern Indiana. The nursing staff performed vaccinations using standard of care for pain for four weeks, then the implementation of Buzzy® was used for four weeks. Data were collected using two pain rating scales associated with specific ages. The Face Legs Activity Cry Consolability Scale (FLACC) was used to observe the pain behavior of children ages newborn to two years. The Wong-Baker FACES Pain Rating Scale was used for children ages three to seven years. Data were collected through electronic medical record and then analyzed through chi-square for demographic information and chi-square for independence for outcomes on pain. The demographic differences between the two groups were statistically insignificant. The FLACC outcome scores were significantly different between the pre- and post-intervention groups ( $\chi^2(4, N=28) = 12.48, p < 0.05$ ) while the FACES outcome scores were insignificant ( $\chi^2(3, N=28) = 5.94, p > 0.05$ ). The results showed that future research for pain management strategies during needle-based procedures is still essential for improving patient comfort, as well as improved patient compliance.





## CHAPTER 1

### INTRODUCTION

#### Background

Vaccinations are responsible for promoting human health and reducing morbidity and mortality from infectious diseases. However, the usual method of administration of vaccinations is through needle puncture, which is often painful. In children and adults, vaccinations are the most common painful needle procedure, with an estimated 12 billion injections given per year (CDC, 2019; McMurtry et al., 2015). Of course, the majority of these vaccinations occur in children between the ages of newborn and 18 years because of the amount of booster vaccines that are due in these important years of growth (CDC, 2019). The patients may consider the pain from these vaccinations as “mild” and others would report a much higher degree of pain and fear. Thus, children often report receiving a shot as one of the most feared and painful experiences. These concerns over vaccinations do not simply vanish over the course of childhood; in fact, needle apprehension is quite common in adults as well (McMurtry et al., 2015). The most severe cases of needle fear are even diagnosed as needle phobia. Needle phobia is an extreme fear of medical procedures involving injections or needles. For most people, this fear starts to develop around the age of four or five and can last until about 10 years of age due to a bad immunization experience (Buzzy, 2019; McLenon & Rogers, 2018). At this point, individuals who are compliant with vaccination schedules will have received well over a dozen needle sticks. The issue results when there is a failure to implement evidence-based pain management strategies during these procedures. The repeated painful procedures in early childhood without benefit of treatment represents a high risk for the development of severe levels of needle fear (McMurtry et al., 2015).

There are multiple psychopathological perspectives that could be applied to help understand the factors that lead to high levels of needle fear and phobia in children and the adults that they will become. Some predisposing factors may include genetic factors, life events, or temperament (McMurtry et al., 2015). It is thought that humans are biologically prepared to fear needles given fear of pain and injury. Female gender and younger age have also been shown to be significantly related to needle phobia. Precipitating factors refer to triggering events that have led to the onset of current fear. These events could be a history of fainting, significant pain, or severe bleeding that occur as a result of a needle procedure (McLenon & Rogers, 2018). Perpetuating factors are those that maintain a problem once it has become embedded and established in the person's life. A horrible experience with a needle procedure becomes embedded in the person's mind so much so, that the distressing memory of the needle related incident causes significant fear towards any other needle related procedure (McMurtry et al., 2015).

This fear of needles can lead to several negative consequences, particularly when the person has a moderate to high level of fear towards needle related procedures. For instance, children or adults that have needle fear are more likely to experience a higher amount of pain from the procedure (McMurtry et al., 2015). The patients are then more likely to fear health care professionals in general, leading to avoidance of receiving health assistance including vaccinations in growing children (McLenon & Rogers, 2018). People that fear needles may also experience a higher risk for the occurrence of fainting or seizure that can lead to serious safety concerns. Similarly, children that are fearful of needles may flail or run away from any needle procedure leading to restraint that could cause injury to the patient or the person trying to restrain (McMurtry et al., 2015). All of these consequences can lead to noncompliance. Thus, coming to the conclusion that an intervention is needed to help prevent these fears from occurring.

### **Data from the Literature Supporting Need for the Project**

Children are exposed to several different needle-related procedures, whether it is for routine immunizations, intravenous insertion (IV), or venipuncture. The pain related to these procedures can vary from mild to severe, which can generate high levels of anxiety and fear (Ballard, Khadra, Adler, Trottier, & Le May, 2019). Needle phobia is estimated to affect approximately 10-20% of the population. While a majority of needle phobias are due to genetic factors and the experience of vasovagal reflexes, the remaining 30% are considered classic phobias arising due to traumatic experience (Susam, Friedel, Basile, Ferri & Bonetti, 2018). Some patients even perceive that medical personnel completed procedures without any effort to relieve pain or anxiety increasing the amount of risk for needle phobia (Redfern, Chen, & Sibrel, 2017). It is recommended that whenever possible children should not be exposed to painful procedures. However, when unavoidable, interventions should be provided to limit the painful experience. Despite an increase of pain stemming from medical procedures and the distress associated with this, research indicates that pain management continues to be suboptimal (Moadad, Kozman, Shahine, Ohanian, & Kurdahi, 2016). Since this is the case, in recent years the interest for managing painful procedures to reduce emotional and physical effect has been on the rise (Canbulat, Ayban, & Inal, 2015; Inal & Kelleci, 2017).

Needle pain management has included several options that are both pharmacological and nonpharmacological, such as topical anesthetic creams, vapocoolant sprays, and distraction techniques. Topical anesthetic creams (5% lidocaine-prilocaine cream, 4% tetracaine gel, 4% lidocaine cream, and iontophoresis) provide local anesthesia, but require a minimum application of 15 to 60 minutes, which is not feasible in busy outpatient office settings (Inal & Kelleci, 2017; Sabiner et al., 2015). They have also been associated with reports of adverse reactions (Canbulat

et al., 2015). Vapocoolant spray is a skin-cooling technique and contain chemicals that produce an instantaneous cooling effect. The coldness reduces the sensation of pain, however, there was no difference in pain associated specifically with vaccinations. While, these pharmacological inventions have some proof of being helpful in reducing pain, there were significant issues related to these interventions. These issues were mainly related to adverse effects, increased cost, excessive amount of time between placement of cream and needle procedure, and special training for staff (Canbulat et al., 2015; Inal & Kelleci, 2017; Canbulat Sabiner et al., 2015). Nonpharmacological interventions are typically divided into physical and behavioral techniques. Physical techniques include, but are not limited to, massages, counter-stimulations, ShotBlocker (numerous blunt contact points to saturate the sensory signals around an injection), stroking, and vibration. While some of the behavioral techniques include music distraction, cartoon distraction, communication, singing, reading, playing a game, video games and kaleidoscopes (Canbulat et al., 2015; Redfern et al., 2018; Canbulat Sabiner et al., 2015). Each of these methods is useful in practice and has data to support it, but there is no single integrated method to optimize pain relief. What is necessary to provide the most benefit for these patients is something that is easy to use, inexpensive, and a rapid method to relieve pain (Canbulat et al., 2015).

In recent years, the Buzzy® device, a vibrating motor with ice pack, combines multiple approaches by supplying cold analgesia, tactical stimulation, and distraction (Redfern et al., 2018). The vibration and cryotherapy device is able to provide pain relief via the Gate Control Theory, meaning that prolong cold simulation blocks the pain signals, while the vibration distracts the patient from a painful needle procedure (Canbulat Sabiner et al., 2015). This type of intervention is advantageous because it is cost effective since it is easily reused through a simple sterilizing technique. It is also simple for a nurse to use independently (Bergomi, Scudeller,

Pintaldi, & Dal Molin, 2018). This device has proven effective in the pediatric population, and also demonstrated superior pain relief in children while confirming the feasibility of its use in a fast-paced care practice (Canbulat et al., 2015).

### **Data from the Clinical Agency Supporting Need for the Project**

The clinical agency where this Evidence Based Practice (EBP) project was conducted was a family practice office in Northern Indiana. The clinic is part of the larger organization. It is run by a family physician and a nurse practitioner, who provide equal amount of care to the patients. Within the office there are four medical assistants that assist in providing care. The physician, nurse practitioner, office manager, and preceptor liaison all approved of this project, and the family physician served as the site facilitator. This office opened in this specific location in January of 2019, but was previously providing care in a neighboring town. The care that is provided at this office ranges in complexity and age. Patient's ages ranged from newborn to elderly, and the care can range from a simple vaccination to a more complex treatment for hypertension, diabetes, and other chronic multifaceted conditions. The practice sees approximately 100 patients per week, and about 20 of those patients are children. According to the electronic medical record technician (2019), the number of vaccinations given in the last six months prior to the start of the project for children, ages newborn to 18 years, was well over a 1000.

With a large number of vaccinations given every year to children in the clinic, there is an increased need for an intervention to prevent pain. Currently, the only intervention that is used is comfort from the child's parent through holding and consoling. There is also no policy or protocol in place for an invention during vaccinations. That being said, the clinic and agency

were incredibly receptive to an intervention that may help decrease the pain for children, and thus make their experience more tolerable.

The small town where this project is located is in the northern part of Indiana, close to the Michigan border. The total population of this town is around 1,600, with 87% of the population being white and 10% Hispanic or Latino (Suburban Stats, 2018). The area is not diverse, and thus there is a high chance of seeing more patients that are of white race. Within this populace there is a population of over 200 families with a least one child (under 18 years) that lives within the home (Suburban Stats, 2018). The median household income for people that live in this town is \$45,500 and the average unemployment rate is 4.1%. At least 62.6% of the population has received at least a high school diploma and currently 17.91% of the population is enrolled in school. This clinic also serves more than just the local community, they also contribute to care of patients in neighboring towns.

### **Purpose of the Evidence-Based Practice Project**

The purpose of this EBP project was to decrease the pain associated with vaccinations in children. The rise of needle phobia has increased the need for an intervention to be used during needle-based procedures to help improve patient care and influence compliance with health care. A protocol for the providers in practice was developed in order to provide proper intervention for children who were undergoing routine vaccinations, the most common needle-based procedure in children. EBP projects incorporate a systematic search for evidence and critical appraisal of the findings with clinical expertise with patient's and family's values and preferences to provide the best practice and patient care (Schmidt & Brown, 2019) Thus, this project explored the use of an intervention to help relieve pain during vaccinations, and ultimately improve the child's experience, and decrease fear of future needle-based procedures. In order to improve and

influence the child's experience, a search for the best practice options to help intervene in the vaccination process was conducted. Through the research process, several options for intervention were found to be effective, however, the Buzzy® device, created by Pain Care Labs, with a combination of vibration and cryotherapy proved to be highly useful and cost-effective in a busy clinical practice.

### **PICOT Question**

Clinical questions are often formatted through the PICOT model. PICOT is a useful mnemonic device that stands for: patient population or patient condition or interest (P), intervention of interest (I), comparison of interest (C), outcome of interest (O), and time (T) (Schmidt & Brown, 2019). Using this model, a PICOT question was developed for this project. The PICOT question of interest is: In pediatric patients, under 7 years of age, receiving routine vaccinations (P), what is the effectiveness of using non-pharmacological Buzzy® device (I) compared to standard practice of no comfort policy (C) in helping to promote a decrease in pain measured by the FLACC or Wong-Baker Faces Scale (O) during an eight-week period (T)?

### **Significant of the EBP Project**

In the primary care setting, the most common pain-producing procedure in children are vaccinations (Redfern et al., 2018). With the rise of needle phobias and non-compliance for healthcare procedure, it is important for an intervention to be used in children undergoing vaccination. Since there is no current practice in place for comfort for pain during vaccinations at this clinic, it is especially important for a protocol to be in place to improve a child's experience with healthcare providers. Often children are fearful of going to the doctor's office because they are worried about needing a vaccination. Using an intervention to distract from the pain of receiving a vaccination will help improve the child's pain and influence their feelings towards



healthcare providers. Ultimately, this project will seek to improve compliance, not only for child, but also for the adults that they will become in the future. It is important to influence children when they are young, when they are building their trust in individuals. This will then proceed into adulthood and further compliance with healthcare procedures.

## CHAPTER 2

### EBP MODEL AND REVIEW OF LITERATURE

#### Evidence-Based Practice Model

After thoroughly reviewing the many EBP models, the Johns Hopkins Nursing Evidence Based Practice Model (JHNEBPM) was selected as a guide for the EBP project development, planning, and implementation. This model in particular was created for the purpose of placing EBP into the clinical setting, thus taking what is found in literature to transform how practice is done (Melnik & Fineout-Overholt, 2015). The literature found to support a change in practice for implementing an intervention for pain during vaccinations in children was systematically reviewed for best practice. A synthesis of best practice concepts was included for the implementation in this EBP project.

#### Overview of EBP Model

The JHNEBPM was created in 2002 when the organizational leadership at The Johns Hopkins Hospital recognized a gap in the standard for nursing practice of implementing research results (Melnik & Fineout-Overholt, 2015). The goal of the model that was to create a more useful product for bedside nurses and an easier way for evidence based practice to be embedded into everyday nursing care. The JHNEBPM includes core research and non-research evidence within the triad of professional nursing practice. The key influences behind the model are concepts associated with internal organizational factors like culture, environment, and staffing, and external factors such as accreditation, quality measures, and standards (Melnik & Fineout-Overholt, 2015).

These ideas are placed into practice through the implementation of what JHNEBPM refers to as the PET process. PET consists of three phases for implementation: practice questions,

evidence, and translation. Within these phases there are 19 steps that allow nurses to walk easily through the process of implementing EBP into the clinical setting (Dang & Dearholt, 2017; Melnyk & Fineout-Overholt, 2015). The first phase, practice question, focuses on recruitment of the interprofessional team to help develop the EBP question. Once the EBP question is defined then key stakeholders are identified, and the responsibility of the project leadership is established. The final stage of this phase is scheduling a team meeting to go over the next steps in the process. During the evidence phase, research is conducted both internally and externally. This evidence is then appraised on its quality and summarized for easier understanding. Once all the evidence has been gathered, the overall synthesis strength and quality of the evidence can provide the information needed to know if this practice should be implemented. This will allow the team to develop recommendations for change and identify the need for change in practice. The final phase is translating this evidence into practice. This process takes several steps due to the process of identifying the right location, feasibility of the change, and appropriateness of recommendations. Once this has been recognized the project leader can start creating an action plan and secure the support needed to carry out the action plan. The next logical step is to implement the action plan and evaluate the outcomes. These outcomes are reported to those involved in the action plan, and next steps are identified if needed. Finally, if the change in practice was seen as significant, then the modification can be fully implemented into everyday practice (Dang & Dearholt, 2017).

### **Application of EBP Model to DNP Project**

The JHNEBPM is useful for application in project planning, implementation, and translation into practice. Using the 19-step process and three phases, this model was used for implementation of the Buzzy® device during vaccinations in pediatric patients. In the first phase,

the key stakeholders were identified, and a discussion on the use of the Buzzy® device was addressed. The key stakeholders involved include a physician, nurse practitioner, several medical assistances, and the participants plus their families. The evidence surrounding the use of Buzzy® was discussed with the key stakeholders, which was identified as being useful for practice in the pediatric population that is seen at this family practice office. Since, the change is necessary for the practice, use of the Buzzy® device will be implemented into practice.

### **Strengths and Limitations of EBP Model for DNP Project**

There are significant strengths that are associated with the use of the JHNEBPM for this DNP project. This EBP model was specifically created and designed for nurses, by helping them easily translate evidence into practice. This is one of the largest strengths for any DNP project because it creates an easy format for nurses and advanced practice nurses to use. The model is also useful by integrating practice, research, and education, all of which are necessary when creating and implementing a change into practice. Additionally, this model can be used in both inpatient and outpatient settings. This model was initially designed with bedside nursing in mind, but it is also easily translated into the outpatient setting. As Melnyk and Fineout-Overholt (2015) state, “The JHNEBPM Model applies to clinical, learning, and operational question in any setting where nursing is practiced, and in academic setting at schools of nursing at the undergraduate and graduate level” (p. 416). These areas are all important strengths for DNP project planning and implementation, however, one of the key areas that separates the JHNEBPM from other EBP model is the fact that it relies on an open system. Through the PET process, the best practices to answer practice questions are identified, which leads to improvement in all areas of practice including clinical, learning, ad operations. However, at any point throughout the model, new ideas and questions may arise, thus triggering a new EBP cycle.

Since this model is an open system, it can be influenced by several different factors like the culture of the practice, the patients that are seen in the practice, and standards/quality measures. This makes the model dynamic and allows for openness to all areas that make affect the EBP project process. This makes it easier for the key stakeholders and project manager to identify potential threats to the EBP project (Melnik & Fineout-Overholt, 2015).

However, every model is not without its weaknesses. As previously mentioned, this model is rather complex and detailed. This includes the complexity of the openness aspect of the model. With every EBP project there are multiple factors that are influencing the project itself, while identifying these areas can be helpful it can also be time consuming and cause the project to change altogether (Melnik & Fineout-Overholt, 2015). Likewise, the 19-step process can be rather burdensome compared to other models that are more succinct in their steps. For this reason, the JHNEBPM is more useful in an individual office setting rather than at the organizational level (Newhouse, Dearholt, Poe, Pugh, & White, 2004).

### **Literature Search**

#### **Sources Examined for Relevant Evidence**

The research for this project started in Cochrane and Joanna Briggs Institute (JBI), as they often provide high quality evidence to support practice. The search began with Cochrane, using the same limiters throughout which included: the year limiter of 2014 to 2019 and the English language. However, different key terms were used to help produce the most evidence. The first search included the key terms: *“Buzzy” AND pain\* AND vaccin\* OR immuniz\**. Of these results, two of the articles were relevant to my topic. From this search, the decision was made broaden the search terms by using needle instead of focusing specifically on vaccinations. Thus, the search terms for Cochrane became, *“Buzzy” AND pain\* AND needle*. This resulted in

nine trials, of which, four were relevant for the project, however one was a duplicate from the previous search. While still searching in Cochrane, the term “*Buzzy*” was changed to be included in all text instead of the standard title abstract keyword. The search was then “*Buzzy*” AND *pain\**, creating an even broader range for article obtainment. This resulted in one systematic review, that was not relevant due to lack of use of the Buzzy® device in the review, and 25 trials. Based on the trials, there were ten that were significant for the project, with three of the ten being duplicated from previous searches. A final search was completed in Cochrane as several mesh terms that could have resulted in further evidence. The key terms used for the final search were: *Vibrat\* AND pain\* AND cryotherapy*, resulting in nine trials. Four of the trials were duplicates from previous searches and two were new that were helpful for the project. In total, 13 trials were significant for the project. After reviewing these articles, they were then narrowed down to include only those that identified pediatric patients (0-18 years old) undergoing a needle-based procedure (IV, blood specimen collection, or vaccination/IM injection) utilizing only Buzzy® (not in combination with other interventions) against a control group (standard of practice) and identified pain as a major outcome being measured. The setting of the research project did not matter because this would have drastically limited the amount of useful evidence. Additionally, one of the articles focused specifically on cognitively delayed children, while significant, it was a very specific group of children. Based off of these inclusion/exclusion criteria, six relevant articles were selected.

Following the Cochrane database search, JBI was then assessed for quality systematic reviews or any relevant evidence. Again, using the same limiters throughout each search, which included only limiting the date range between 2014 to 2019. JBI was searched using the key terms, “*Buzzy*” AND *Pain\* OR discomfort*, which provided four results that included

recommended practices and evidence summaries, but no systematic reviews. Then completing a more detailed search that included the key terms of *“Buzzy” OR vibrat\* AND inject\* OR needle\* AND pain\* OR discomfort*. The results included 11 different recommended practice, systematic review protocols, and evidence summaries. Using one of the recommended protocols for citation chasing, one article was found to be relevant and it was also one that had been found in Cochrane. Likewise, one of the systematic review protocols also provided relevant articles through citation chasing, but the articles were the same ones found in Cochrane, thus providing no new evidence.

Without much success in JBI, the search continued in CINAHL. In all of the searches conducted in CINAHL the limiters of date range between 2014 to 2019, Scholarly Journals, and English language were included. The first search terms included: *“Buzzy” OR “cooling vibrat\*” AND pain\* OR discomfort*, which resulted in 15 different articles. Of the 15 articles, one systematic review was found to be relevant and 11 other articles were also significant. In total 12 articles were significant, however seven of the articles were also found in Cochrane. Following this search, the key terms were simplified to include, *“Buzzy” OR “cooling vibrat\*” AND needle*. This recorded seven results, four that were relevant, but not new from the previous search. The final, search included *vibrat\* AND cool\* AND pain*. There were nine results from these terms, but only one was relevant and it was also found in previous searches. In total, after taking out duplicate results, only the systematic review was left as an additional reference.

The last three databases that were searched included Medline, Nursing & Allied Health (ProQuest), and Health Source. In all three databases, very simple key terms were used that included *“Buzzy” AND pain\**. The limiters that were included were date ranges between 2014 and 2019 English language, peer review, full-text, and scholarly journals. In Medline, there were

27 results. Of those 27 results, 13 were relevant to the project, but they were all articles that were duplicates of ones found in Cochrane and CINAHL. In Nursing & Allied Health, there were 25 results. Of those 25, only one was based on inclusion and exclusion criteria listed previously, and it too had been found in a previous search in Cochrane and CINAHL. Likewise, Health Source produced five results, with one that was relevant and also found in both CINAHL and Cochrane. The search was then conducted using the key terms, *“Buzzy” AND pain AND vaccin\* OR immun\**. In Medline, this resulted in three clinical trials, one was not relevant due to the participants being adults and the other two articles were previously found in CINAHL and Cochrane. Nursing & Allied Health had five results, all of which were not used for this project due to the lack of inclusion and exclusion criteria. Health Source contained no results using the key words listed.

Once most of the articles were found, then reviewing of the citations in the systematic review to find out if there were other articles that should be included in my final literature review. Several of the articles that were used as evidence in the systematic review were also found while searching the databases, however, there were two articles that were searched for further significance. Only one of the articles was within the inclusion criteria of pediatric patients undergoing a needle-based procedure using Buzzy® to improve pain, however, it included the use of Buzzy® in combination with other interventions. Thus, both articles were not selected for final review due to lack of agreement with the inclusion and exclusion criteria.

For the final search, to prove that saturation had been reached and exhausted all efforts, a hand search was completed for evidence found on Buzzy®’s website. On the website, it includes a section on different research articles that have used Buzzy® for pain relief. Thus far, almost all the articles that were selected were included on the Buzzy® website. However, there were two



articles that were reviewed more closely. These articles ended up not being included in the final review because of exclusion criteria (Table 2.1).

### **Levels of Evidence**

The source that was selected for use in leveling the evidence was the Johns Hopkins Nursing Evidence-Based Practice Research Appraisal tool. This leveling tool provides both appraisal for the level of evidence and the quality of the evidence. When appraising the level of evidence, there are three simple questions for both appraisal of randomized control trials and systematic reviews. If the answer is “yes” to all three questions then the level of evidence is a level 1 (highest level of evidence), however, if there are any that are “no,” that lowers the level of evidence based on how many answers were “no.”

While reviewing the selected articles for the final literature review, they were all level 1 evidence. The systematic review that was used checked all the boxes for being included in the level 1, as well as all seven of the randomized control trials were also level 1 evidence. Thus, making the articles all high evidence in the ranking according to the tool used.

### **Appraisal of Relevant Evidence**

The benefit of using the Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal tool allows for quality appraisal as well. It is a simple appraisal tool that allows the user to answer 12-15 simple questions about each article (depending on if it is a RCT or systematic review). The user walks step-by-step through an article to make sure all the important information is present to make for a quality study and article. Then once all the “yes” or “no” questions have been answered, it is up to the user to identify if all the areas are being met

Table 2.1

*Evidence Search Table*

Database	Yielded	Duplicates	Reviewed	Accepted
Cochrane	68	8	13	6
JBI	32	0	1	0
CINAHL	31	11	12	1
Medline	30	13	13	0
ProQuest	30	1	1	0
Health Source	5	1	1	0
Citation Chasing	5	0	4	0
Total	201	34	45	7

to make the evidence high quality, or if there are areas of weakness making the quality either good or low/major flaws. If the quality is high then the articles are consistent with generalizable results, have a sufficient sample size, designate a specific control group, define conclusions, and use consistent recommendations for future practice that are based upon evidence.

While closely reviewing all seven articles selected for use to support the evidence for practice change, the articles that were found only ranked as high or good quality. Any articles that were of low quality were dismissed from use in the final literature review. Overall all of the articles that were selected for final review were considered level 1 evidence with either high or good quality.

**Level 1 evidence.** Ballard et al. (2019), recently published a systematic review and meta-analysis discussing the use of the Buzzy® device for pain management in children undergoing needle-related procedures. The search method conducted for this systematic review included searches in PubMed, Ovid MEDLINE, Ovid All EBM Reviews, Ovid Embase and Ovid PsychINFO, and CINHALL between the dates of inception until December 18, 2017. The database searches were completed with the assistance of a librarian with special training and skills in literature searches. The authors had strict inclusion and exclusion criteria that included only randomized control trials which compared the Buzzy® device to a control group of infants, toddlers, children, and adolescents from 28 days to 18 years old who required a needle-related procedure, such as immunization, venipuncture, IV insertions, intramuscular or subcutaneous injections. The studies that were included must also use a combination of both vibration and cooling therapy, not individually. Finally, there was not a language restriction set in place during the search. Based on this inclusion and exclusion criteria, a total of nine randomized control trials were included in the systematic review and seven were included in the meta-analysis.

In total, 1,145 children and adolescents (age range between 3 to 18) were included between 2011 and 2018. The studies had a range of control groups that were used to compare with the Buzzy® device. These groups either had an absent nonpharmacological intervention/no intervention control group, vapocoolant spray and/or topical anesthetic, and distraction cards. The needle procedures also varied across studies, three included IV insertions, two included venipunctures, two others included both IV and venipuncture, and the last two included immunizations. The primary outcome measured was needle-related procedural pain intensity that was evaluated during or immediately after the procedure by at least one pain scale, which included self-reported by the visual analog scale, numerical rating scale, verbal rating scale, or faces scale; parent-reported or observer-reported through two different scales including the Children's Hospital of Eastern Ontario Pain Scales or the Faces Legs Activity Cry Consolability Scale (FLACC). The results of these studies showed that the Buzzy® device demonstrated a statistically significant effect on reducing both self-reported pain and parent-reported and/or observer-reported pain during needle-based procedures. Through critically appraising this study, it was placed as a level 1 and high quality based on the JHNEBP tool.

Bergomi, Scudeller, Pintaldi, and Dal Molin (2018), conducted a randomized control trial for the purpose of evaluating non-pharmacological techniques, vibration combined with cryotherapeutic topical analgesia by the use of the Buzzy® device and animated cartoons, in relations to pain and anxiety relief during venipuncture in children. The study focused on children between the ages of five and 12 years old. The child and their parents received thorough instruction for the potential use of a non-pharmacological intervention during venipuncture. The final consented participants included 150 children undergoing venipuncture. The participants were randomly split into any of the four groups: no intervention, animated cartoon distraction

alone, animated cartoon with Buzzy® device, and Buzzy® device alone. The randomization occurred through the use of an independent statistician using the Strata 13. This was immediately followed by the preparation of numbered opaque sealed envelopes, which included the allocated groups. The envelopes were then divided into the appropriate locations and to the appropriate participants. The pain and anxiety scale were then explained to the participants, with the primary measurement being focused on pain. The pain scale used to evaluate the intensity of pain was the Wong-Baker Faces Pain rating scale. The secondary outcome were the nurses' and parents' perception of the child's pain. The comparison of continuous variables between all four of the groups were statistically analyzed by the way of one-way analysis of variance. Comparison of the categorical variables was performed by way of the Pearson's  $\chi^2$  test. A p-value of  $<0.05$  was considered to be statistically significant. The data were run through the Strata computer software. Overall, the results concluded that children's perception of pain was less in the non-pharmacological intervention groups compared with no intervention. Buzzy® was highly effective in children that were younger than nine years of age ( $p = 0.04$ ). Additionally, there was also a significant efficacy among the Buzzy® and cartoon group ( $p = 0.04$ ) for the nurse's perception of child's pain and in the Buzzy® group alone for the mother's perception of the child's pain ( $p = 0.002$ ). Overall, the study proved to be a level 1 with good quality based on analysis using the JHNEBP tool.

Canbulat Sahiner, Ayban, and Inal (2015), conducted a randomized control trial that was conducted for the purpose of investigating the effect of external cold and vibration stimulation via the Buzzy® device on pain and anxiety levels in children that were undergoing peripheral intravenous cannulation. The sample for inclusion criteria included patients that were aged 7 to 12 years who were having IV cannulation performed. Participants were excluded if they had a

break in the skin where the device was to be placed, critically ill or had nerve damage, neurodevelopmental delay, verbal difficulties, use of analgesic within the last six hours, or history of syncope due to blood specimen or immunization. Based on this criteria and parental consent, 176 children were randomly assigned to the non-intervention group or the cold and vibration therapy group. Immediately after the IV cannulation procedure, the child's pain level was assessed through self-report via the Wong-Baker Faces Scale and the visual analog scale. The data were analyzed with the SPSS version 15.00, which resulted in a significant  $p$  value of  $<.05$ . The pain and anxiety levels of the children were compared with  $t$  test and demographic information was compared with frequency and  $\chi^2$ . The results of the study proved to be significant in the external cold and vibration stimulation group, lower pain levels were recorded for both self-reported scales compared to the non-intervention group ( $p < .001$ ). Based on the information reported in this article and through thorough analysis using the JHNEBP tool, the article is considered a level 1 with good quality.

Canbulat, Inal, and Akbay (2015), reported a study that investigated the effect of combined stimulation of skin with external cold and vibration via the Buzzy® device measuring the pain and anxiety levels during immunization in children. This study was a randomized control trial conducted during routine school immunizations in children that were all seven years old receiving the same required DTaP vaccination via intramuscular injection. Those that were not include in the study were participants that had break in the skin where the device was to be used, nerve damage in the affected extremity, critically ill or unstable, neurodevelopmental or verbal difficulties, or history of syncopal episodes with blood specimen or immunizations. The 104 children that had parental consent were randomized based on a computer-generated table or random numbers into two equal groups. Children that were in the control group did not receive

an intervention whereas those in the invention group received external cold and vibration stimulation via the Buzzy® device. The level of pain was assessed in each child using the Wong-Baker FACES pain rating scale and verbal reports. The data were then analyzed using the SPSS software 15.00. The  $p$  value less than 0.05 was considered significant in this study. The comparison between the pain levels was analyzed using  $t$  test, while the demographic data were compared using frequency and chi-square tests. The results showed that self-reported procedural pain levels were significant between the study groups ( $p = .001$ ). The experimental group had significantly lower pain levels ( $p = .001$ ) than the control group. Based on the JHNEBP tool, the study was considered a level 1 with good quality based on lack of details included in the study design.

Inal and Kelleci (2014), completed a randomized control trial investigation into the effect of external cold and vibration stimulation via Buzzy® on pain and anxiety levels of children during blood specimen collection. The inclusion criteria for this study included children between the ages of 6 and 12 years who required blood tests. The participants were excluded if there was a break in the skin where the device was to be placed; if they had nerve damage in the affect extremity; if they were chronically ill or unstable, neurodevelopmental delay, verbal difficulty; if they had some sort of analgesic within the last six hours; or have a severe history of syncopal episodes during needle-based procedures. For participants and parents that consented to the study, demographic information was collected and thorough instructions on the device and pain scales were administered. Those that consented included 120 children, and they were randomized on the basis of a computer-generated table of random numbers into two equal groups. The control group did not undergo any intervention, however the experimental group received the application of cold and vibration stimulation via Buzzy®. After the procedure, pain levels were

assessed by self-reports, parents' and the observer's report. The pain scale that was used for reporting was the 0-10 Faces Pain Scale-Revised (FPS-R). The pain scale has been used in over 140 studies and is accepted as a well-established measuring tool. The data were then analyzed with SPSS version 15.0; a  $p < 0.05$  was considered to be significant. The data were compared using  $t$ -test for pain and chi-squared and frequency for demographic information. The external cold and vibration stimulation group had significantly lower pain levels in the self-reported, parent reported, and observer reported pain levels compared to the control group ( $p < .001$ ). The details included in this study were consistent with an analysis of level 1 and high-quality rating per JHNEBP tool.

Moadad, Kozman, Shahine, Ohanian, and Badr (2016), completed a randomized control trial that explored the use of external cold and vibration via the Buzzy® device and its effect on pain ratings in children, their parents, and nurses during peripheral IV insertion. The participants that were selected to be included were 4 to 12-year-old children. The exclusion criteria included those with a break in the skin where the device is to be placed; if they are critically ill or unstable; history of taking an analgesic in the last four hours; history of a syncopal episode during blood draws; and history of neurodevelopmental delay or verbal difficulties. Based on these inclusion and exclusion criteria, there was a total of 48 that were analyzed. The children were randomized into a control group and intervention Buzzy® group. Randomization occurred by flipping a coin (heads = control; tails = intervention). Pain was measured using the Wong-Baker FACES Pain Rating Scale. Pain was reported by the child, their parents, and the nursing staff. All three were blinded to each other's pain rating score, as to decrease the bias on the score. The statistical data were analyzed using the SPSS for Windows version 22. The demographic information was described using frequency and means/standard deviations. The



pain scores were compared using ANOVA. The authors of this study also looked closely at separate age groups by using univariate analysis and dividing the ages into two groups; 4 to 7 years and 8 to 12 years. The results of study concluded that children in the control group reported higher scores on the Wong-Baker FACES Scale than those that were in the intervention group ( $F(2/45) = 7.07, p = 0.011$ ), nurses also rated children's pain higher when the Buzzy® device was not applied ( $F(2/45) = 6.7, p = 0.014$ ). When comparing ages, the results showed that younger children had significantly higher pain scores in the control group versus those in the Buzzy® intervention group ( $F(2/19) = 8.96, p = 0.007$ ). However, pain ratings by mothers were not significantly different between groups. Overall, the Buzzy® intervention group was significant when patient-reported pain and nurse-reported pain was involved, making the device still useable and helpful in practice. The authors of this study concluded that Buzzy® may be most beneficial in younger children because this age group is more easily distracted and would not focus on the needle as much as older children. Through thorough analysis using the JHNEBP tool, this study would be a level 1 with high quality evidence.

Redfern, Chen, and Sibrel (2018), completed a randomized control trial for the purpose of measuring the impact of combining cold and vibration on pain scores during routine vaccination in children. The children involved in this study were between the ages of 3 and 18 years of age and undergoing a routine vaccination at their annual well visit. The participants were excluded if they had used Buzzy® before; if they had a history of Reynaud's syndrome or sickle cell disease with extreme sensitivity to the cold; there was a break in the skin where the device was to be used; nerve damage present in the affected extremity; history of neurodevelopmental delay or verbal difficulties; or analgesia used within the past six hours. The number of injections that the participant was to receive did not excluded them from the study. Verbal and formal consents

were filled out for those that agreed to participate per the patient and the legal guardian. There were 51 children undergoing vaccinations that consented to participate in the study, 26 were randomized to the Buzzy® group and 25 to the control group. Randomization was completed by way of a randomization schedule created by the research staff using [www.randomizer.org](http://www.randomizer.org) prior to the beginning. Folded paper tags with group assignments were placed into sequentially numbered, sealed envelopes and opened at the time of consent. An explanation of the device was given during the consent process, the authors felt that child's expectation and perception of the pain may have bias due to knowing how the device works so they required participants to rate how much they thought the injection would hurt prior to the procedure. However, the study still measured pain following the procedure by way of self-reported, parent-reported, and observer-reported. All of the assessments of pain used the Wong-Baker Faces Pain scale. The data collected were analyzed using the SAS version 9.2. Chi-squared and *t*-tests were used to investigate the categorical and continuous variables. The associations between parent, child, and observer ratings, as well as the association of pain ratings with satisfaction ratings were analyzed using Pearson correlation coefficient. Significance level was set at  $p < 0.05$ . When comparing the post-procedural pain ratings given by children, those that were in the Buzzy® group reported significantly lower pain than those in the control group (mean difference of  $-2.39$ ; 95% CI  $-0.48$  to  $-4.24$ ;  $t = -2.53$ ;  $p = 0.015$ ). The mean pain reported between those receiving one injection and those receiving more than one was not statistically different ( $p = 0.36$ ). When comparing ratings of post-procedural pain for the observers and parents, the observers rated pain lower ( $p = 0.04$ ), while the parents were not significant compared to the control ( $p = 0.09$ ). The details of this study were significant and through analysis using the JHNEBP tool it was found to be a level 1 with high quality evidence (Table 2.2)

Table 2.2

*Evidence Summary Table*

<b>Author(s)</b>	<b>Purpose</b>	<b>Design/Quality Rating</b>	<b>Sample</b>	<b>Measurement/Outcome</b>	<b>Results</b>
Ballard, A., Khadra, C., Adler, S., Trottier, E. D., & Le May, S. (2019).	The purpose of this study was to systematically review the use of Buzzy® in several needle-related procedures and how it affected pain and anxiety.	Systematic Review <ul style="list-style-type: none"> <li>• Level 1</li> <li>• High Quality</li> </ul>	Randomized control trials comparing Buzzy® device to control in infants, toddlers, children, and adolescents from 28 days to 18 years old who required a needle-related procedure. A total of 1145 children were involved in this systematic review.	9 RCT were used in the systematic review; 7 RCT were used in the meta-analysis. They measured pain during needle based procedures using a range of different pain rating scales.	Buzzy® device on self-reported pain, the overall effect was found to be significant (SMD -1.12; 95% CI: -1.53 to -0.71; P <0.0001).

Bergomi, P., Scudeller, L., Pintaldi, S., & Dal Molin, A. (2018).	The purpose of this study was to evaluate vibration combined with cryotherapeutic topical analgesia using Buzzy® devices and animated cartoon on pain and anxiety during venipuncture.	Randomized Control Trial <ul style="list-style-type: none"> <li>• Level 1</li> <li>• Good Quality</li> </ul>	Children between the ages of 5 and 12 years were included. This study included 150 children.	The study measured animated cartoon distraction alone, animated cartoon with Buzzy® device, and Buzzy® device alone. The child's perception of pain was evaluated using the Wong-Baker Faces Pain rating scale.	The secondary analysis showed that Buzzy® was highly effective in children younger than 9 ( $p = 0.04$ ). Also, a significant efficacy was recorded in the Buzzy® and Cartoon group ( $p = 0.04$ ) for the nurse's perception of the child's pain, and in the Buzzy® group for the mother's perception of the child's pain ( $p = 0.002$ ).
Canbulat Sahiner, N., Ayhan, F., & Inal, S. (2015).	The aim of this study was to investigate the effect of external cold and vibration stimulation via Buzzy® on the pain and anxiety level of children during peripheral	Randomized Control Trial <ul style="list-style-type: none"> <li>• Level 1</li> <li>• Good Quality</li> </ul>	The sample consisted of 176 children ages 7 to 12 years who were randomly assigned to two groups: a control group that received no peripheral IV cannulation intervention and	The children's pain levels immediately after the peripheral IV cannulation procedure were also assessed via self-reports using the Wong Baker Faces Scale (WBFC) and the visual analog scale (VAS)	The children in the external cold and vibration stimulation group had significantly lower pain levels than the control group according to their self-reports (both WBFC and

	intravenous (IV) cannulation		an experimental group that received external cold and vibration via Buzzy®		VAS scores; $p < .001$ ).
Canbulat, N., İnal, S., & Akbay, A. (2015).	This study investigated the effect of the combined stimulation of skin with external cold and vibration via Buzzy® on the pain and anxiety levels in children during immunization.	Randomized Control Trial <ul style="list-style-type: none"> <li>• Level 1</li> <li>• Good Quality</li> </ul>	Inclusion criteria were 7-year-old children who required immunization (DTaP). The study included 104 participants.	The pain and anxiety levels of the children were assessed using the Wong-Baker FACES scale and Children Fear Scale.	The self-reported procedural pain levels showed significant differences between the study groups ( $P = .001$ ); the experimental group (1.38 6 1.92) had significantly lower pain levels ( $P = .001$ ) than the control group (3.42 6 3.10). Also, the experimental group's pain levels based on the two observers' reports (1.31 6 1.36 and 1.15 6 1.27) were significantly lower than that of the control group (4.85 6 2.72 and

Inal, S. & Kelleci, M. (2014).	To investigate the effect of external cold and vibration stimulation via Buzzy® on pain and anxiety levels of children during blood specimen collection.	Randomized Control Trial <ul style="list-style-type: none"> <li>• Level 1</li> <li>• High Quality</li> </ul>	The sample consisted of 120 children aged from 6 to 12 years undergoing phlebotomy	Immediately after the blood specimen collection procedure, the children's pain levels were assessed via self-report, the parents' and the observers' reports using Faces Pain Scale-Revised (FPS-R).	4.60 6 2.94) (P 5 .001 for both). Children in the external cold and vibration stimulation group had significantly lower pain levels by self-report, parent report, and observer report than the control group ( $p < .001$ ). The results indicated that children reported higher scores on the WBFPS when they did not have the "BUZZY®" applied, $F(2/45 = 7.07, p = 0.011$ , nurses also rated children's pain higher when the "BUZZY®" was not applied, $F(2/45 = 6.7, p = 0.014$ .
Moadad, N., Kozman, K., Shahine, R., Ohanian, S., & Badr, L. K. (2016).	To investigate the effects of external cold and vibration via the "BUZZY®" on pain ratings of children, their parents and nurses during peripheral IV insertion, to measure the time to a successful IV insertion and to assess the factors that are associated with pain perception of children.	Randomized Control Trial <ul style="list-style-type: none"> <li>• Level 1</li> <li>• High Quality</li> </ul>	The participants included 4-to 12-year-old children who required an IV insertion at either the pediatric unit of the AUBMC or the Children's Cancer Center of Lebanon. Included 48 children in the study.	The dependent variable was pain as assessed on the Wong-Baker FACES Pain Rating Scale.	Younger children had significantly higher pain scores

Redfern, R. E., Chen, J. T., & Sibrel, S. (2018).	The purpose of this study was to measure the impact of combing cold and vibration on pain scores during routine vaccination.	Randomized Control Trial <ul style="list-style-type: none"> <li>• Level 1</li> <li>• High Quality</li> </ul>	Children who were at least 3 to 18 years old were eligible present for well-child with immunization and Buzzy® naïve. This study included 50 children.	Pain and anxiety were measured by the child using the Wong Baker Faces Pain Scale during immunizations.	in the “No Buzzy®” group compared to the “Buzzy®” group, $F(2/19) = 8.96$ , $p = 0.007$ In comparing the post-procedure pain ratings given by children, those in the Buzzy® group reported significantly lower pain than those in the control group, with a mean difference of $-2.39$ (95% CI $-0.48$ to $-4.24$ , $t = -2.53$ , $p = 0.015$ ).
---	--	--	--	---	---

---

## Synthesis of Critically Appraised Literature

### **Buzzy® (cryotherapy and vibration).**

The use of pharmacological and nonpharmacological treatment for pain and anxiety during needle-based procedures has become increasingly important over the past several years since the rise of needle-related phobias in the pediatric population. Some of the most significant treatments have been the use of topical anesthetic creams, vapocoolant sprays, and distraction techniques (cartoons, blowing up a balloon, blowing bubbles, etc) (Ballard et al., 2019; Bergomi et al., 2018; Canbulat et al., 2015; Redfern et al., 2018). However, more recently, there has been an indication for a combination treatment option that has proven equally as significant. The combination treatment that has become increasing popular across the nation is a device called Buzzy®. It is a combination of vibration and cold therapy (cryotherapy) that comes in a bee shaped design (Ballard et al., 2019; Canbulat et al., 2015; Moadad et al., 2016; Redfern et al., 2018). The bee shaped device combines the cooling ice pack wings and vibrating motor body. The way that this device works is through The Gate Control Theory. This theory suggests that pain is transmitted from the peripheral nervous system to the central nervous system, where it is modulated by a gating system in the dorsal horn of the spinal cord (Ballard et al., 2019; Canbulat et al., 2015; Moadad et al., 2016; Redfern et al., 2018). The afferent pain-receptive nerves, that is the A-delta fibers and slower C fibers carrying pain messages, are blocked by faster non-noxious motion nerves. The prolonged cold and vibration stimulates the C fibers and may block the A-delta pain signals. The addition of cold treatment may also result in enhanced activation of supraspinal mechanism, raising the body's overall pain threshold (Ballard et al., 2019; Canbulat et al., 2015; Moadad et al., 2016; Redfern et al., 2018).



While Buzzy® works great for the treatment of pain perception during needle-based procedures, it is also cheap and effective almost immediately. One of the biggest disadvantages to using a topical anesthetic or vapocoolant spray is that they can take up to 45 minutes for full effect and they can also be quite costly (Canbulat Sahiner et al., 2015). However, Buzzy® works almost instantly. The reusable ice pack wings are frozen solid prior to patient use and once they are pulled out of the freezer, they are connected to the battery operated vibrating bee body. The bee is then placed on the patient's needle site for 30 seconds, and then moved 3 to 5 cm proximal to the site immediately prior to the needle stick (Canbulat Sahiner et al., 2015; Moadad et al., 2016). In total, this device takes far less time, making it ideal for busy clinics and emergency departments. Additionally, since the device is easily cleaned off between patients for reuse it also saves money compared to other products that are not reusable (Ballard et al., 2019; Inal & Kelleci, 2014).

### **Pain.**

As previously stated, the largest reasoning for the use of Buzzy® is to limit pain and anxiety. Pain is always the primary outcome of measurement when dealing with a patient undergoing a needle-based procedure. More often this is based on the fact that pain is much easier to measure than anxiety. However, it can still be difficult to measure pain in children due to subjectivity, as well as the understanding of the child (Ballard et al., 2019). There are several different scales that are used to measure pain and anxiety, as well as different scales for different age ranges. Since Buzzy® is used most commonly in pediatric care, the most frequently used pain scale is the Wong Baker Faces Scale (Ballard et al., 2019; Bergomi et al., 2018; Canbulat et al., 2015; Canbulat Sahiner et al., 2015; Inal & Kelleci, 2014; Moadad et al., 2016; Redfern et al., 2018). This scale consists of six cartoon faces that range from neutral expression (0 = very

happy/no pain) to a screaming face (10 = worst pain imaginable). This scale is most useful for children that are at least three years to around seven years of age because at this age range they can understand cartoon faces and emotions, but they are not fully able to understand their pain on a scale from 0 to 10. Another commonly used pain scale is the Visual Analog Scale. This scale tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot be easily measured directly (Canbulat et al., 2015). That means this scale is usually a horizontal line, 100 mm in length, with two-word descriptors at each end. One end will say “no hurt” and the other end will say “worst hurt”. The child will then make a mark on the line at the point where he or she feels represents his or her perception of pain. Then the point of pain is determined by measuring where this mark lies in accordance with the left-end of the line (Ballard et al. 2019; Canbulat et al., 2015). The last commonly used pain scale for children that can be used during needle-based procedures is the Face Legs Activity Cry Consolability Scale (FLACC). The FLACC scale can be used on children between the ages of two months and seven years, however, it is not commonly used in children after the age of three unless they are non-verbal or sedated (Ballard et al., 2019). Each of the five categories in this scale are assessed and scored from 0-2, 0 being the child shows no particular expression, relaxed, quiet, and not crying, or 2 being the child is crying, restless, screaming, and not consolable. The scores are then added up to get the overall pain rating between 0 (no pain) and 10 (severe pain) (Ballard et al., 2019).

It is clearly seen that these scales can be used in all different age ranges, but they can also be used from a different perspective. The FLACC scale, is often reported based off of an observer-reported perspective. That is the observer or health care professional assesses the patient and gives the patient a certain score for pain based off of the patient’s behavior (Ballard et al., 2019). The Wong Baker Faces Scale and Visual Analog Scale are both scales used from

the patient perspective, parent perspective, or observer. All of these different perspectives were used throughout research when assessing Buzzy® and the amount of pain the child experienced during the needle procedure or immediately after the procedure was completed (Ballard et al., 2019).

### **Age specific.**

The age for the use of Buzzy® during needle-based procedures has not been verified, however, research has shown that Buzzy® tends to work best in children that are younger than nine years of age. After nine, children are able to be distracted using more visual aids like video games or cartoons (Bergomi et al., 2018). However, there is still evidence to support the use of Buzzy® throughout the lifespan, including children of all ages (between 0 and 18). Much of the research conducted is associated with children that are at least three years of age and range up to 12 years of age. This is the most commonly used age range because it allows researchers to only use one pain rating scale, as well as children are able report their own pain by this age (Ballard et al., 2019; Canbulat et al., 2015).

### **Best Practice Model Recommendation**

Based on the reviewed literature, for children under seven undergoing immunization the use of Buzzy® is highly recommended in helping to reduce pain. While, anxiety is also a huge reason for the use of Buzzy®, pain is the primary measurement throughout research, thus the focus for using Buzzy® is primarily on the management of pain (Inal & Kelleci, 2014). Buzzy® was specifically useful in ages younger than nine, as previously mentioned, children older than nine tend to have less pain when distracting using something visual (Bergomi et al., 2018). Additionally, when addressing what pain scale to use when assessing pain during needle-based procedures the use of the Wong Baker Faces Scale was ideal for children over three years of age.

It was also the most frequently used scale since it has good reliability and validity (Ballard et al., 2019; Canbulat Sahiner et al., 2015). However, when looking at children less than three, the FLACC scale was also proven to be beneficial in measuring pain from the observer's point of view (Ballard et al., 2019).

Buzzy® has been proven to be useful for many kinds of needle-based procedures, however, the most commonly performed needle-based procedure in the outpatient family care practice involving pediatric patients is vaccinations (Redfern et al., 2018). With vaccinations at the focus, Buzzy® will be used according to the recommendations in best practice. The Buzzy® wings will be removed from the freezer a couple minutes prior to the procedure and connected to the vibrating body. The child will be allowed to play with the Buzzy® device so that they feel comfortable with it. The Buzzy® device will then be applied to the site for stimulation for 30 seconds. When the vaccination is to be given, Buzzy® will be moved about three to five centimeters above the site and continue through the end of the procedure (Ballard et al., 2019; Redfern et al., 2018).

## **CHAPTER 3**

### **IMPLEMENTATION OF PRACTICE CHANGE**

Initiating a change in practice was created to help improve patient compliance, pain perception, and overall patient experience in pediatric patients receiving vaccination. In recent years there has been more research focused on controlling pediatric pain during needle-based procedures to help improve patient experience and decrease needle phobias. Needle phobias as a child has been shown to be positively correlated with noncompliance in adult patients (Ballard et al., 2019). One terrible needle-based experience as a young child can lead to years or decades of fear. Thus, increasing the need for an intervention and change in practice to help fight the rising numbers of patients with needle phobias.

#### **Participants and Setting**

This EBP project took place at a family practice office in the northern part of Indiana. The office sees an array of ages across the lifespan, as well as a variety of care between common and complex patient diagnoses. There are two providers in the practice, a masters-prepared NP and a physician. The office is part of a larger healthcare organization that owns the practice, however, it is run by the one physician in the practice. This physician has over 20 years of experience in practice, while the NP has over 2 years of experience. The physician in the practice was selected as the project preceptor for this EBP project. The project preceptor granted implementation of the EBP project on May 23, 2019, which was also approved by the preceptor liaison for the healthcare organization, as well as the office manager. For a family practice office, this office sees a high number of children in need of vaccinations during their well-child visits. Since this case is true, it made the project preceptor understand how important it was to improve patient satisfaction by limiting the fear and pain that is associated with vaccinations.

Vaccinations in the office are given by any of the four medical assistants on staff at the practice. All the medical assistant staff members are trained to give vaccinations and are competent to give vaccinations to a person of any age. Currently, the medical assistants do not participate in any sort of comfort measure during vaccination, nor do they measure the amount of pain the person endures during the procedure. The medical assistants widely accepted the practice change and implementation of the use of the Buzzy® device during vaccination.

The participants for this project were recruited during their appointments for routine vaccination during either a well-child visit or a simple nurse visit for an immunization. The age range of participants is from zero to seven, as those are the years when children receive the most vaccinations, as well as when the needle fear starts to be introduced. The participants can be male or female gender and come from any demographic or race background. The participant's parents must have the ability to speak and understand spoken and written English to sign the consent form for using the Buzzy® device. The number of injections required during the appointment was not a factor in either inclusion or exclusion from this project. Participants that were excluded from the project included those that have a history of extreme sensitivity to coldness; nerve damage present that would affect the extremity being injected; neurodevelopmental delays or verbal difficulties; or there was a break or abrasion in the skin where the device would be placed during the procedure.

### **Pre-Intervention Group Characteristics**

Prior to implementation of the Buzzy® device, four weeks of measuring pain among children newborn to seven was completed. The pre-intervention group consisted of 12 participants that received routine vaccinations. The group was made up of six females and six males with a range of ages from the youngest at two months and the oldest four years. The most

common age was two years or 24 months. Of the 12 participants, eight of the participants were under three years of age with four then being three years and older; meaning eight participants had their pain level measured using the FLACC scale, while the other four were measured using the Wong Baker Faces Scale. The participants did not have a previous history of painful procedures, however, there was a difference in the number of shots given; 8 of the 12 participants received four vaccinations, one received three vaccinations, two received two vaccinations, and one received one vaccination. Among the participants, there was not a significant variation in race. A majority of the participants were Caucasian, making up nine of the pre-intervention participants. The other three participants consisted of two African Americans and one that is unknown.

### **Intervention**

The intervention for this project was developed based on EBP recommendations and from these, a detailed protocol and/or implementation guideline was created for use during vaccination. The intervention includes the use of cryotherapy and vibration in the form of the Buzzy® device. The combination of intervention has been proven highly effective, as it combines two different ways of interrupting nerve impulse. Since the combination therapy has been shown to be most effective, it was thus implemented into practice.

Upon arrival to the practice, patients that met the inclusion criteria were asked to join the project via parental approval. The legal guardian of the patient was requested to sign a consent form prior to the implementation of the Buzzy® device (see Appendix B). If the consent was signed, then the child and/or parent played with the Buzzy® device prior to injection, so that they felt comfortable with the product. While the child and/or parent was becoming acquainted with the device, the icepack wings were removed for a couple minutes of thawing prior to

placement on the participant's skin. When the participant was ready for the procedure to begin, the Buzzy® device was placed on the injection site. The device was vibrating, while also cooling with the icepack portion of the device. It remained on the site for 30 seconds prior to injection. When the injection was taking place, the device was moved just above the site still continuing to vibrate and providing cold therapy. The injection was then given to the participant. Immediately after the vaccination was completed, the participant was scored for pain that was experienced. In children that were younger than three years of age, the Face, Legs, Activity, Cry, and Consolability Scale (FLACC Scale) was used to assess the pain. While, children that were over three years of age were assessed using the Wong-Baker Faces Pain Rating Scale. After the assessment was completed, the medical assistant placed the pain score in the patient's electronic medical record.

Prior to the start of implementation of the intervention a brief in-service was completed to educate the medical assistances and the providers on the use of the Buzzy® device. A PowerPoint presentation was completed to inform the staff about how the Buzzy® device worked, how to use the different pain scales, and what would be required for documentation in the electronic medical record. Throughout the project reminders were emailed and food incentives were given to let the staff know the progress with the project, as well as the appreciation for participation in this practice change.

### **Comparison**

Prior to implementation of the intervention, data were collected for four weeks to obtain the average pain rating score of children receiving vaccinations that were between the ages of zero and seven years. The reason that this comparison is taking place is to identify not only the need for an intervention for pain, but also to assess how high the average pain (FACES Scale



participants) and/or how the behavior of pain (FLACC Scale participants) was compared to the post-intervention group. Currently, the practice has no comfort measures in place for children that are receiving routine vaccination. Since, vaccinations are the largest routine pain-producing procedure in children it is important to identify interventions that can help limit the pain that is afflicted during these procedures.

### **Outcomes**

The primary outcome that has been identified for the project is pain rating after injection. Children that are under three years of age, will be assessed using the FLACC Scale. The FLACC Scale instructions include five parts that are: face, legs, activity, cry, and consolability. The participant is given a rating for each part that ranges from a zero to two. The minimum pain score is a zero and the maximum score is a 10. The participant has zero pain if their face has no particular expression or smile; their legs are normal position or relaxed; they are lying quietly with normal position and moves easily; the person is not crying; and the participant appears content and relaxed. The maximum score of a 10 consists of the participant having frequent to constant quivering chin and clenched jaw; kicking or drawn-up legs; arched, rigid, or jerking; crying steadily, screams, sobs, and frequent complains; and difficulty to console or comfort (The Department of Health, 2013a). Often children fall somewhere between these two extremes. For example, a child may show a grimaced facial expression (rating 1), with relaxed legs (rating 0), body that is tense (rating 1), a small whimper (rating 1), and appears to be reassured when held (rating 1). For this child, the score would indicate a pain rating of four, however this is from simple observation of behavior. This scale is used when self-reported pain is not possible, which is the case with children that are under three. Children under three do not have the capacity to understand how to rate their own pain, thus the FLACC scale is an interpretation of pain

behavior. It takes careful decision and observation of pain behaviors in order to indicate what the pain score may be for the specific patient. According to The Department of Health (2013a), the instructions for using this assessment tool include: observing the person for at least two to five minutes, observe legs and body uncovered, reposition patient or observe activity, and finally initiate consoling intervention if needed.

The FLACC Scale has readily been used in children and critically ill adults that are unable to verbally report pain. There are several studies that have looked at the reliability and validity of the FLACC Scale. In one such study, the FLACC score correlated significantly with Checklist of Nonverbal Pain Indicators (CNPI) scores, thus supporting excellent criterion validity in adults ( $p = 0.963$ ;  $P < .01$ ). Additionally, the FLACC Scale and another pain scale called COMFORT were highly correlated ( $p = 0.849$ ;  $P < .01$ ), supporting criterion validity in children (Voepel-Lewis, Zanolli, Dammeyer, & Merkel, 2010). Using the same study, reliability was proven to be significant as well. It was proven that agreement among each of the observers was excellent for each category in the FLACC Scale, as well as for the total FLACC score. This supports the interrater reliability of the tool for assessing pain. Finally, internal consistency was excellent with a Cronbach alpha of 0.882 (Voepel-Lewis et al., 2010).

In addition to the FLACC Scale, the Wong-Baker FACES Scale was also used to assess pain in children that were old than three years of age. The tool was originally created with children for children to help them communicate their pain. The scale has a series of faces that range from a happy face at zero to a crying face at 10. Again, children often fall somewhere between these two extremes of “no hurt” to “hurts like the worst pain” (Wong-Baker FACES Foundation, 2016). The child is given an explanation that each face is for a person who feels happy because he/she has no pain (hurt) or sad because he/she has some or a lot of pain. The

child is then asked after the procedure what face best describes how he/she is feeling (The Department of Health, 2013b).

The Wong-Baker FACES Pain Rating Scale has been used in multiple research studies involving children over three years of age. One study conducted in an emergency department focused on the validity of the Wong-Baker FACES Scale (Garra et al., 2010). The Wong-Baker FACES Scale was tested for correlation with the Visual Analog Scale (VAS), a scale that is similar but does not include visual faces to show what the pain may look like for the patient. A test for homogeneity of variance across the FACES Scale categories was not significant. Additionally, agreement between the FACES Scale and the VAS was excellent ( $p = 0.90$ ; CI = 0.86 to 0.93) (Garra et al., 2010). For reliability of the FACES Scale, a systematic review was examined that looked closely at three different “face” scales, one of them being the Wong-Baker FACES Scale. It was determined that the test-retest reliability was  $r > 0.5$  and correlation between self-report and observational scores were  $r > 0.4$ . Furthermore, when children were given the choice between faces scales, they preferred the Wong-Baker FACES Scale over all other face scales (Tomlinson, von Baeyer, Stinson, & Lillian, 2010).

Using both of these pain rating scales, data were collected by the medical assistants who gave the vaccination. After the vaccination was given, the medical assistants assessed the pain rating score using the appropriate scales. Once the rating was determined, the medical assistant documented the pain rating score in the participant’s electronic medical record, along with what scale was used for the patient.

Demographic information for the project was collected using the electronic medical record. The project manager looked closely at the child’s age, racial differences, and if there has

been any experiences of painful surgeries or procedures in the past. These past experiences could affect how the child experiences pain now, thus making it an important factor to measure.

Following the completion of the implementation of the intervention, the project manager collected the data from the electronic medical record for analyzing. The data were not removed from the electronic medical record or taken to the project manager's home. All the data collection took place at the project site, as there was no access to the health system's electronic medical records outside of the project site. Once all the data were collected, the pre-intervention and post-intervention pain scores were analyzed via chi-square of independence. The demographic data were also analyzed using Chi-square and t-test for independence.

### **Time**

The project timeline lasted for eight weeks starting on August 26<sup>th</sup>, 2019 and going until October 18<sup>th</sup>, 2019. The first four weeks of the project was focused on collecting preliminary data. Since the office currently does not use any pain tools to assess pain during vaccinations, the project manager collected data on pain ratings prior to the use of the Buzzy® device. The project manager also collected demographic information to assess for the variation in race, ages that are seen most often, and painful procedures (surgeries, broken bones, dental procedures, and other painful experiences). Following the four weeks of pre-intervention, the Buzzy® device was implemented for four weeks to assess pain rating scores post-intervention. The reason this time of year was selected was due to the increase of influenza vaccinations given during the fall months.

### **Protection of Human Subjects**

Throughout the entirety of the project human subjects were protected from any risk or harm. The project manager went through the proper education for protection of human subjects,

as well as completed an ethics course through a certified DNP program in the fall of 2018. The CITI Program entitled, “Social Behavioral Educational Research: Basic Course” was also completed in April 2019 by the project manager to fulfil the Valparaiso University requirements to begin this project. The project manager completed an Institutional Review Board (IRB) Questionnaire in July 2019 to plan what sort of review was expected for this project. Upon completion, the exemption form for Valparaiso University IRB was completed per the questionnaire response on July 17, 2019. Prior to implementation of the Buzzy® device, the participants and parents/legal guardian were thoroughly educated on the device, the project, and the risk factors associated with participation. Any questions that the participant or legal guardian had about the project were completely answered. If the legal guardian approved that their child could participate then consent was obtained by the legal guardian. The participants and guardians were informed that confidentiality would be upheld, that participation was completely voluntary, and if at any point they did not want to participate they would be exempt without issue. The data from the participants were collected in the health care system’s electronic medical records and are secure via password protection. Following this collection, the data were entered into the project manager’s personal computer. The participants did have any personal identifiers in the project manager’s personal computer. The computer was password protected both on the home screen, as well as in the analysis program to help insure protection of any participant information.

## CHAPTER 4

### FINDINGS

The purpose of this EBP project was to implement the use of cryotherapy and vibration via the use of the Buzzy® device in order to improve patient comfort and reduce pain that is associated with receiving a vaccination. Patient outcomes were measured using the FLACC pain rating scale for children two years and under, as well as the FACES pain rating scale for children three years and older. The baseline pain scores were collected over four weeks prior to the implementation of the Buzzy® device. Once implemented, pain was once again measured for another four weeks. Analyzation was completed for both demographic characteristic and pain score comparison.

#### Participants

**Size.** During the implementation of the project, there were a total of 16 participants that received guardian consent for the use of the Buzzy® device during vaccination. Each of the participants had recorded pain scores that were associated with their respective ages and scales that were used. Likewise, the pre-intervention group was measured in the same way, however there were only 12 participants in total in that group.

**Demographics.** Demographic characteristics were collected for the post-intervention group using the same process as the pre-intervention group. A thorough search of the electronic medical records provided the information for gender, age, race, previous painful procedures, and the number of vaccinations received during the visit. The post-intervention group consisted of 10 females and 6 males. The age range of the post-intervention group was two months to five years of age, with the most common age being four months. Of those who participated, 10 were measured using the FLACC pain scale and 6 were measured using the FACES pain scale. Like

the pre-intervention group, none of the participants had a history of previously painful procedures. The number of vaccinations that were given ranged from one vaccine to five vaccines. There were four participants that received one vaccine, seven received three vaccines, four received four vaccines, and one received five vaccines. The race of the post-intervention participants included nine Caucasians, two African Americans, three Hispanics, and two unknowns. Descriptive statistics regarding pre-intervention and post-intervention demographic data are presented in Table 4.1.

### **Changes in Outcomes**

This EBP project addressed the following PICOT question, “In pediatric patients, under 7 years of age, receiving routine vaccinations (P), what is the effectiveness of using non-pharmacological Buzzy® device (I) compared to standard practice of no comfort policy (C) in helping to promote a decrease in pain measured by the FLACC or Wong-Baker Faces Scale (O) during an eight-week period (T)? The primary outcome of pain was measuring using either the FLACC scale for those two years and under or the Wong-Baker Faces Scale for those three years and older.

**Statistical testing.** Data were entered into the Statistical Package for Social Sciences (SPSS) Version 22 for statistical analysis. The text *How to use SPSS: A step-by-step guide to analysis and interpretation* by Cronk (2017) was also utilized to help guide the process of analysis and interpretation of project data. A t-test was completed for comparison of pre-intervention and post-intervention pain scored for both pain scales. A t-test was also used to compare pre-intervention and post-intervention demographic information on patient age and number of vaccinations. A chi-square statistical analysis was completed for comparison of the rest of the demographic information which included patient gender, previous painful procedure,

Table 4.1  
*Demographic Characteristics*

Demographic	Pre-Intervention Frequency (%)	Post-Intervention Frequency (%)
Number of Participants	12 (100%)	16(100%)
Age		
Mean/SD	24 months/2.23	21 months/2.87
Range	2 months – 4 years	2 months – 5 years
Gender		
Male	6 (50)	6 (37.5)
Female	6 (50)	10 (62.5)
# of Vaccinations		
1 Shot	1 (8)	4 (25)
2 Shots	2 (17)	0 (0)
3 Shots	1 (8)	7 (44)
4 Shots	8 (67)	4 (25)
5 Shots	0 (0)	1 (6)
Race		
Caucasian	9 (75)	9 (56)
African American	2 (17)	2 (12.5)
Hispanic	0 (0)	3 (19)
Unknown	1 (8)	2 (12.5)



and patient race. Statistical significance for all analyses was determined as  $p < 0.05$ .

**FLACC scale.** The perception of pain for children two years and younger was scored using the FLACC scale, which rates pain based on five different items that are ranked with a score of zero to two for each item. These five items include face, legs, activity, cry, and consolability. The participants pain was rated based on their facial expression following vaccination, the restlessness of their legs, their overall squirminess, the amount of crying, and finally, their ability to be easily consoled. The total of these items adds up to a score between 0 and 10, with 0 being rated as no observed pain to 10 being severe pain observed following vaccination. A chi-square for independence was completed to compare scores from the pre-intervention group to the post-intervention group. The mean for the pre-intervention group was 4.5 ( $sd = 2.2$ ), and the mean for the post-intervention group was 1.2 ( $sd = 0.41$ ). A significant difference between the pre-intervention and post-intervention group was found ( $\chi^2(4, N=18) = 12.48, p < 0.05$ ).

**FACES scale.** Participants that were three years and older, scored their pain rating using the Wong-Baker FACES scale. This scale rates pain on a scale from 0 to 10 using increments of two. Each number coincides with a picture of a cartoon face depicting the amount of pain that the participant might be in after vaccination. The participant was asked to select which pictures accurately depicts the amount of pain that was experienced. A chi-square for independence was completed to compare scores from the pre-intervention group to the post-intervention group. The mean for the pre-intervention group was 3.5 ( $sd = 0.71$ ), and the mean for the post-intervention group was 1.5 ( $sd = 0.71$ ). No significant difference between the pre- and post-intervention group was found ( $\chi^2(3, N=10) = 5.94, p > 0.05$ ).

**Demographic stats.** To make an accurate comparison of the two groups it was important to verify that the groups were similar in regard to their age, number of vaccinations given, race, and previous history of a painful procedure. A *t*-test was completed to compare both the pre- and post-intervention ages and number of vaccinations. The participants in the pre-intervention group had a mean age of 24 months ( $sd = 2.23$ ), and the mean age of the post-intervention group was 21 months ( $sd = 2.87$ ). No significant difference was found between the pre- and post-intervention group ages ( $t(11, N=28) = 0.799, p > 0.05$ ). Likewise, there was no significant difference found when comparing the number of vaccinations ( $t(11, N=28) = 1.23, p > 0.05$ ). The mean for the pre-intervention number of vaccinations was 3.3 ( $sd = 1.07$ ), and the mean for the post-intervention number of vaccinations was 2.7 ( $sd = 1.37$ ). The rest of the demographic information was compared using chi-square analysis. A chi-square test of independence was calculated comparing the genders of both the pre- and post-intervention groups. No significant relationship or difference was found between the two groups ( $\chi^2(1, N=28) = 0.438, p > 0.05$ ). Another chi-square of independence was calculated comparing the race of both the pre- and post-intervention groups. Again, no significant relationship or difference was found ( $\chi^2(3, N=28) = 2.82, p > 0.05$ ). Participants in both groups had never experienced a previously pain procedures, and therefore there was not a need for any statically significant analysis as both groups were exactly same in this case.

**Reliability and validity.** The reliability and validity of each tool utilized to evaluate pain outcomes was assessed. The FLACC scale was used to evaluate pain for participants two years and younger, while the Wong-Baker FACES scale was used to evaluate pain for participants three years and older. There is consistent evidence to support the reliability and validity of the FLACC scale (Voepel-Lewis et al., 2010). The FLACC and FACES scale were tested for

validity through the comparison of associating the two scales together. A Pearson Correlation was computed to show the reliability of the FLACC and FACES scales. The results were considered medium reliability with a score of 0.635. The FLACC scale could not be tested for validity due to each item in the scale having an individual score, and for this project only a total number was computed therefore it cannot be tested against other like scales. Though, it has been thoroughly tested for validity in the literature. Likewise, the FACES scale was not able to be tested for validity due to similar circumstances, as well as the inability to extract specific data from other studies that were completed in a similar way. Although, the FACES scale has been used numerous times in literature and is considered very valid in other studies.

## **CHAPTER 5**

### **DISCUSSION**

This EBP project served the purpose of answering the PICOT question, “In pediatric patients, under 7 years of age, receiving routine vaccinations (P), what is the effectiveness of using non-pharmacological Buzzy® device (I) compared to standard practice of no comfort policy (C) in helping to promote a decrease in pain measured by the FLACC or Wong-Baker Faces Scale (O) during an eight-week period (T)?” The project specifically examined the impact of using cryotherapy and vibration protocol via the Buzzy® device during vaccinations, and the possible improvement of pain and/or comfort through the use of such interventions. This chapter will thoroughly explain and interpret the project findings, as well as evaluate the application of the EBP model which was used to help guide this project. Project strengths and limitations will be discussed, along with consideration of implications for future practice, theory, research, and education.

#### **Explanation of Findings**

The project findings somewhat supported the effectiveness of combining cryotherapy and vibration for pain comfort during vaccinations for children under seven years of age. The results were consistent with the literature for children that were under three years of age, but inconsistent with the literature for children that were aged three years to seven years. Participant findings, which include sample size and demographic characteristics, will be discussed. Outcomes for the individual pain tools will also be explained.

#### **Participant Findings**

The information reported within the high quality, current literature, included a larger sample size of participants undergoing needle-based procedures using the Buzzy® device, thus a

larger sample size for this project was expected. The sample size was more limited due to the specific age range that was included in this project, whereas in the literature reviewed the inclusion population typically consisted of children newborn to 18 years of age. The sample population for the pre-intervention group was equal among males and females, whereas the post-intervention group included more females than males. This was consistent with all of the literature reviewed, as there was not a consistent number of males or females used in any of the studies. Some of the literature reviewed had more females, while other studies had more males that were included. Likewise, the literature that was reviewed included no significant difference between the pre-intervention and post-intervention groups, which was consistent with the results of this project. Only one of the reviewed literature included race as a demographic feature. The participants within that study included more African American participants compared to this project that was predominately Caucasian. The reviewed study was completed in Toledo, OH where the population is 65% Caucasian and 27% African American (Redfern et al.), which is surprising considering the larger number of African American patients that were seen. However, for this project, the larger number of Caucasian included was consistent with the population in the area. The studies that reviewed the number of vaccinations given were also consistent with the number reported for this project. There was a larger mixture of anywhere from one to five vaccines given in the literature review, which was seen in this EBP project as well. In the literature review and in this project, there was no evidence to suggest previous painful procedures and essential leaving no data for comparison.

### **Pain Results**

Statistically significant results were found when the FLACC pre-intervention group was compared to the FLACC post-intervention group. The group consisted of children that were

under three years of age. The mean score for the 8 participants in the pre-intervention group was 4.5, while the mean score for the 10 participants in the post-intervention group was 1.2. The scores recorded indicated a decrease in pain when using the Buzzy® device for vaccinations. The results of this portion of the EBP project were consistent with results found in the literature review as it concludes that use of the Buzzy® device for younger children was seen to produce significant reduction in pain (Ballard et al., 2019). Thus, the statistical decrease in pain scores achieved supports the benefit of using the Buzzy® device for comfort when children younger than three years of age receive vaccinations.

While the children under three years of age were considered to have significant results, those that were between the ages of three and seven, using the FACES scale for pain, were not considered significant in this project. However, the lack of statistical significance does not exclude the positive impact that the Buzzy® device has on pain during vaccinations. The mean score for the four participants in the pre-intervention group was 3.5, while the mean score for the six participants in the post-intervention group was 1.5. These mean scores indicate that there was a decrease in pain between the two groups even though it was not considered significant. Part of the reason for the lack of significances may be due to the smaller sample size, as compared to the FLACC group. The FACES group only had a total of 10 participants included in both groups, while the FLACC group had 18 participants in total. The lack of participants is a possible reason for the lack of significance in results. Additionally, the literature that was reviewed included far larger sample sizes when compared to this project, which may account for the fact that those results were all considered to be significant. While the results were surprising, there was still one study that did indicate that the Buzzy® device was more effective in younger aged children. The reasoning could be that younger children are more easily distracted, while older children may be

more focused on the needle (Moadad et al., 2016). The distractibility of the younger participants in this project may have played a role in the significant results for the FLACC group, and the absence of significant for the older participants in the FACES group. Therefore, the results of this project in no way indicate the impact that the Buzzy® device can have for future practice. The decrease in mean score of pain between the two groups indicates that the Buzzy® device was still effective in providing pain relief and was a great benefit to the participants, even though it was not significant.

### **Strengths and Limitations of the DNP Project**

The Johns Hopkins Evidence Based Practice Model (JHNEBPM) served as the EBP model that guided the project. The use of this model aided in the effective implementation of the practice change by providing a framework that the project manager could follow. The successful implementation and results of this EBP project yielded numerous strengths, as well as some limitations. By addressing both the strengths and the limitations of this project, results of this project may be further explained and future related projects may be supported.

### **Strengths of EBP Framework**

The JHNEBPM was a good fit as the EBP framework utilized in guiding this EBP project. The project manager was a beginner in regard to project planning, practice change, implementation, and overall evaluation. Therefore, the detailed steps included in the JHNEBPM aided in the consideration of specific aspects of the project that otherwise may have been missed or disregarded. The JHNEBPM is comprised of three phases that include: practice questions, evidence, and translation. Within the three phases there are 19 steps that were followed through the implementation of this EBP project (Dang & Dearholt, 2017; Melnyk & Fineout-Overhold, 2015). The basic premise of the EBP project was created through the use of the practice question

phase. This phase addressed the identification of the practice problem, issue, or concern that was important for implementation into practice. During experiences within the clinical setting in family practice, the project manager noticed the lack of comfort provided to children during vaccinations apart from family members holding or attempting to comfort the child. After thoroughly study and research for possible solutions for providing comfort, there was strong evidence to support the use of the Buzzy® device. The practice change was then suggested to a Northern Indiana family practice office that immediately developed a plan for the project to unfold. A professional team was formed and the specific EBP question was developed. Evidence was then collected through the evidence phase of the EBP model. All areas of evidence were searched for further evidence to support the use of Buzzy® in practice. Once the evidence was found it was appraised and the quality of each evidence was determined. Summarizing and synthesis of the evidence was completed to help with the development of recommendations for change. The project manager then develop a small educational in-service to discuss the translation into practice. Together, the practice team determined if the change was feasible and appropriate for their specific practice. A plan of action was addressed with the team and the suggestions for how the project would operate were discussed. The project site graciously invested in the Buzzy® devices for the project and for future use. During the implementation of the project, most went according to planned. However, the project manager had to send out emails to frequently remind staff to use the Buzzy® device during the required weeks, as well as recording the respective pain scores in the EMR. Additionally, one of the key stakeholders in the practice change quit half-way through the implementation, which made the project more difficult as there were many new staff members that were not educated on the change that joined the practice site during the project. Modifications were made, and the project manager addressed the



use of the Buzzy® device with the new staff members. Overall, the results of the project were evaluated through the review of the EMR and then run through SPSS for statistical significance. The findings of the project were then reported to the key stakeholders and next steps for dissemination of the findings were determined. Thus far, the project site has adopted the change to practice and continues to use the Buzzy® device for vaccinations, as well as routine blood draws on children and adults.

### **Strengths of the Project**

There were several strengths of this project that were evident. One of the largest strengths was the support from the clinical staff and site facilitator. They greatly believed in the need for practice change and were excited to introduce the Buzzy® device to their patients. This made the project more successful in that they were willing to make the change. Similarly, patients and their guardians willingly accepted the use of the Buzzy® device. Several guardians expressed great satisfaction and a noticeable difference in their child during vaccination. The project would not have been possible if the participants had not been so enthusiastic about the project. Another strength of the project was the simplicity of the project itself. The project was very easy to understand and not extremely time consuming for the staff. This allowed for the project to be realistic in the busy family practice setting. Likewise, with only measuring one outcome it made it easy for the staff to learn the respective pain scales and place the pain score in the EMR. Only measuring a single outcome also made data collection and analysis more straightforward. An additional strength was also the affordability of the Buzzy® device. The Buzzy® device can easily be cleaned off for reuse, making it a great product for busy healthcare facilities that do not want to spend excessive amounts of money on new products for every patient. Although a statistically significant difference was not achieved for children between the ages of three and

seven, this in no way negates the positive impact of the project. As was previously seen, the mean pain score for these children did decrease showing that the Buzzy® device was effective. A statistically significant decrease in pain scores did occur in children that were younger than three years of age. Thus, the overall results of this project were similar to those reported in high quality evidence based on the review of literature.

### **Limitations**

Despite the strengths of this project, there were several limitations worth noting. The small sample size was certainly a limitation to this project. The small sample size was constrained by the short timeline of the project. Additionally, to get a more accurate difference in pain scores it would have been more beneficial to have the same participants for both the pre-intervention and post-intervention groups. However, the short timeline of the project made it difficult as the participants would not need more vaccinations so close together. Of course, the project was not randomized or a double-blind project because the children and/or guardians that participated knew they were receiving the use of the Buzzy® device, as well as the providers/staff knew the participants in the project. The providers and staff were informed of the possible hypothesis, as well as literature review results. This could have caused some bias in reporting of pain scores between the two groups. The staff was also not randomly selected which may have influenced the usual care process. In addition, the project manager was unable to be at the clinic during every child's vaccination due to conflicts schedules. That being said, the staff had to be aware of gaining consents and using the correct pain scoring scale for each participant. There were some situations where consents were not obtained or scores were not recorded in the EMR, thus causing a smaller sample size. There was also a key staff member that quit halfway through the project implementation, which led to further loss of participants due to new

employees not knowing about the project. Finally, during the dissemination portion of the project there was a pandemic of Coronavirus that broke out in the Northern Indiana region causing the project manager to have limited access to the clinic site. However, via conference calls the project manager was still able to communicate with essential staff about how to carry out future practice with the use of the Buzzy® device.

### **Implications for the Future**

This EBP project provided valuable information for the advanced practice nursing profession related to pain relief during vaccinations for children. Future implications for practice, theory, research, and education will be discussed. Such implications can be used to help guide and improve future EBP projects and practice changes, that will positively influence the way pain can be treated during vaccinations.

### **Practice**

The combination of cryotherapy and vibration through the use of the Buzzy® device has been established as one of many best practice options for pain during needle-based procedures in current, high quality literature. This project allowed for the Buzzy® device to become standardized practice during vaccinations at the project site. It was also encouraged for all family and pediatric practices within the organization to adopt this protocol for children receiving vaccinations. This project was supported by the clinical site, and the cost of the Buzzy® devices that were purchased for the project were covered by the clinical site. Other practice sites within the organization have started the process of purchasing Buzzy® devices for their practice. The benefit of the Buzzy® device is that they are relatively inexpensive and reusable making them last longer than a single patient use.

For future EBP projects or related activities there are several considerations to be addressed. Future projects related to the use of Buzzy® device would benefit from a larger sample size and if possible include the same participants for both groups to see if the Buzzy® device has an increased impact on pain scores. Additional recommendations for future projects could include further comparison of the Buzzy® device with other pharmacological and non-pharmacological methods to further standardize the Buzzy® device as the most effective treatment for pain during needle-based procedures. Further comparison could also be completed for all needle-based procedures using the Buzzy® device to seek answers about which needle-based procedure is most effective for the use of Buzzy®. It would also be beneficial for future EBP projects to explore the use of cryotherapy and vibration on adults as the Buzzy® device may be helpful for pain and anxiety during those needle-based procedures as well.

### **Theory**

The use of the JHNEBPM for the framework for this EBP project was helpful in the successful implementation of the Buzzy® device into practice. It allowed for all areas of this project to be fulfilled to the greatest extent, as specific details may have been lost without the guidance from this model. Future projects could also utilize the concepts derived from the JHNEBPM. The model provides detailed steps for the implementation of change into practice in several different specialty areas for inpatient and outpatient settings. However, this model is quite rigorous as it does involve 19 steps within the three phases, future EBP projects would have to take this into consideration when selecting a model.

Future projects may also consider the use of a theoretical foundation to aid in successful implementation. While not in use for this project, Kolcaba's Theory of Comfort may be a great asset for use in future EBP projects. Kolcaba's Theory describes comfort as existing in three

forms: relief, ease, and transcendence. The basis of the theory surrounds the idea that specific comfort needs of a patient are met then the patient experiences comfort in the sense of relief. Ease addresses comfort in a state of contentment. Finally, transcendence is described as a state of comfort in which the patient is able to rise above their challenges. These basic ideas are woven together in the model that addresses the specific health care need, the intervening variable needed for comfort, comfort itself, the health seeking behaviors, the institutional integrity, and best practice/best policies for protocol (Kolcaba & DiMarco, 2005). The use of Kolcaba's Theory of Comfort would be an excellent fit for future EBP projects dealing with pain, as it allows for deeper exploration while still upholding the importance of holistic and patient-centered care.

## **Research**

Further research is needed to explore the effects of Buzzy® device in comparison with other non-pharmacological and pharmacological intervention options for pain during needle-based procedures. It may be that a combination of multiple distraction interventions is more effective than using Buzzy® alone. Although, the additional combination may prove to be too expensive for practices to sustain or too time consuming for busy practices. Thus, there would need to be further research to examine if the combination should become standard of practice. Additionally, further research should look closely at the use of the Buzzy® device in adults. While, needle fears do develop at a younger age, adults may still experience the effects of the fear that started as a child. If shown to be significant then Buzzy® could be used for all ages and all needle-based procedures.

## **Education**

Patient education is an important task and responsibility of the advanced practice nurse. The participants were thoroughly educated on best practice treatment, possible side effects to the use of cryotherapy and vibration, and purpose of the combination therapy for this project. Education was also a main component for staff learning about this project. The staff required an in-service for education on the protocol for change that included the use of the Buzzy® device, as well as perspective pain scales used to assess pain. Additionally, a pamphlet of information from the Buzzy® device company was provided to the participants, which included stories of using the Buzzy® device and further statistical evidence of supporting its use in practice. All of this allowed the participants and staff to become well-informed about this project and the changes need for practice. This project brought incredible light to the importance of standard of practice education in area that is not as well research or studied. Therefore, educating through different resources available may increase the likelihood that others receive the pain relief needed during needle-based procedures.

### **Conclusion**

This EBP project has allowed the site facilitator, clinical staff, and project participants to see the value of using a combination of cryotherapy and vibration through the use of the Buzzy® device for pain during needle-base procedures, specifically vaccinations for this project. The site facilitator and practice manager have expressed their satisfaction with the project and plan to continue to use the device for future needle-based procedures. Additionally, the practice manager that oversees multiple sites plans to incorporate the device into practice at her other sites. Participants also expressed their approval of the use of the Buzzy® device and plan to use the device for future vaccinations. Participants were also encouraged to purchase self-use Buzzy® devices if they change practices and encourage friends with children to do the same.

In conclusion, the results of this project supported the effectiveness of combination cryotherapy and vibration for vaccinations in children as was seen by the improvement in pain scores, which is consistent with current literature. While no statistical significance was achieved for children between the ages of three and seven, there was significance achieved in the children less than three years of age. Overall, in both the older and younger children mean scores for pain did decrease, indicating that the Buzzy® device did reduce pain even when not considered significant. Continuation of the use of the Buzzy® device was encouraged for best-practice purposes. Providers and clinical staff are recommended to incorporate this combination of cryotherapy and vibration protocol as an easy and cost-effective way to continue to provide comfort for those undergoing vaccinations and other needle-based procedure.

## References

- Ballard, A., Khadra, C., Adler, S., Trottier, E. D., & Le May, S. (2019). Efficacy of the Buzzy® device for pain management during needle-related procedures: A systematic review and meta-analysis. *Clinical Journal of Pain*, 35(6), 532–543. <https://doi-org.ezproxy.valpo.edu/10.1097/AJP.0000000000000690>
- Bergomi, P., Scudeller, L., Pintaldi, S., & Dal Molin, A. (2018). Efficacy of non-pharmacological methods of pain management in children undergoing venipuncture in a pediatric outpatient clinic: A randomized controlled trial of audiovisual distraction and external cold and vibration. *Journal of Pediatric Nursing*, 42, e66–e72. <https://doi-org.ezproxy.valpo.edu/10.1016/j.pedn.2018.04.011>
- Buzzy®. (2019). *About Buzzy®*. Retrieved from <https://Buzzy®helps.com/pages/Buzzy®>
- Canbulat, N., Ayhan, F., & Inal, S. (2015). Effectiveness of external cold and vibration for procedural pain relief during peripheral intravenous cannulation in pediatric patients. *Pain Management Nursing*, 16(1), 33–39. <https://doi-org.ezproxy.valpo.edu/10.1016/j.pmn.2014.03.003>
- Canbulat Şahiner, N., İnal, S., & Akbay, A. (2015). The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children. *Journal of PeriAnesthesia Nursing*, 30(3), 228–235. <https://doi-Newhouse, R.,>
- Centers for Disease Control and Prevention. (2019). *Vaccines for your children*. Retrieved from <https://www.cdc.gov/vaccines/parents/index.html>
- Cronk, B. (2017). *How to use SPSS: A step-by-step guide to analysis and interpretation*. (10<sup>th</sup> ed.). Glendale, CA: Pyrczak Publishing.



- Dang, D. & Dearholt, S. L. (2017). *Johns Hopkins nursing evidence-based practice: Models and guidelines* (3<sup>rd</sup> ed.). Indianapolis, IN, USA
- Dearholt, S., Poe, S., Pugh, L. C., & White, K. M. (2004). Evidence-base practice: A practical approach to implementation. *Journal of Nursing Administration*, 35(1), 35-40.
- Garra G, Singer AJ, Taira BR, Chohan J, Cardoz H, Chisena E, & Thode HC Jr. (2010). Validation of the Wong-Baker FACES pain rating scale in pediatric emergency department patients. *Academic Emergency Medicine*, 17(1), 50–54. <https://doi-org.ezproxy.valpo.edu/10.1111/j.1553-2712.2009.00620.x>
- İnal, S., & Kelleci, M. (2012). Relief of pain during blood specimen collection in pediatric patients. *MCN: The American Journal of Maternal Child Nursing*, 37(5), 339–345. <https://doi-org.ezproxy.valpo.edu/10.1097/NMC.0b013e31825a8aa5>
- Kolcaba K, & DiMarco MA. (2005). Comfort theory and its application to pediatric nursing. *Pediatric Nursing*, 31(3), 187–194.
- Melnyk, B. M., & Fineout-Overholt, E. (2015). *Evidence-based practice in nursing and healthcare: A guide to best practice* (3<sup>rd</sup> ed.). Philadelphia, PA: LLW.
- McLenon, J., & Rogers, M. A. M. (2019). The fear of needles: A systematic review and meta - analysis. *Journal of Advanced Nursing (John Wiley & Sons, Inc.)*, 75(1), 30–42. <https://doi-org.ezproxy.valpo.edu/10.1111/jan.13818>
- McMurtry, C. M., Pillai Riddell, R., Taddio, A., Racine, N., Asmundson, G. J. G., Noel, M., Chambers, C. T., & Shah, V. (2015). Far from “just a poke”: Common painful needle procedures and the development of needle fear. *Clinical Journal of Pain*, 31(10), S3–S11. <https://doi-org.ezproxy.valpo.edu/10.1097/AJP.0000000000000272>

- Moadad, N., Kozman, K., Shahine, R., Ohanian, S., & Badr, L. K. (2016). Distraction using the Buzzy® for children during an IV insertion. *Journal of Pediatric Nursing, 31*(1), 64–72. <https://doi-org.ezproxy.valpo.edu/10.1016/j.pedn.2015.07.010>
- Redfern, R. E., Chen, J. T., & Sibrel, S. (2018). Effects of thermomechanical stimulation during vaccination on anxiety, pain, and satisfaction in pediatric patients: A randomized controlled trial. *Journal of Pediatric Nursing, 38*, 1–7. <https://doi-org.ezproxy.valpo.edu/10.1016/j.pedn.2017.09.009>
- Schmidt, N. A., & Brown, J. M. (2019). *Evidence-based practice for nurses: Appraisal and application of research* (4<sup>th</sup> ed.). Boston: Jones and Bartlett.
- Susam, V., Friedel, M., Basile, P., Ferri, P., & Bonetti, L. (2018). Efficacy of the Buzzy® system for pain relief during venipuncture in children: A randomized controlled trial. *Acta Biomed for Health Professions, 89*(6), 6-16. <https://doi-org.ezproxy.valpo.edu/10.23750/abm.v89i6-S.7378>
- Suburban Stats. (2018). *Population demographics for Bristol, Indiana*. Retrieved from <https://suburbanstats.org/population/indiana/how-many-people-live-in-bristol>
- The Department of Health. (2013a). *FLACC pain scale*. Retrieved from <https://www1.health.gov.au/internet/publications/publishing.nsf/Content/triageqrg~triageqrg-pain~triageqrg-FLACC>
- The Department of Health. (2013b). *Wong-baker FACES pain rating scale*. Retrieved from <https://www1.health.gov.au/internet/publications/publishing.nsf/Content/triageqrg~triageqrg-pain~triageqrg-wong>
- Tomlinson D, von Baeyer CL, Stinson JN, & Lillian Sung. (2010). A systematic review of faces scales for the self-report of pain intensity in children. *Pediatrics, 126*(5), 999. Retrieved

from

<http://search.ebscohost.com.ezproxy.valpo.edu/login.aspx?direct=true&db=cin20&AN=104807675&site=ehost-live&scope=site>

Voepel-Lewis T, Zanoliti J, Dammeyer JA, & Merkel S. (2010). Reliability and validity of the face, legs, activity, cry, consolability behavioral tool in assessing acute pain in critically ill patients. *American Journal of Critical Care*, 19(1), 55–62. <https://doi-org.ezproxy.valpo.edu/10.4037/ajcc2010624>

Wong-Baker FACES Foundation. (2016). *Wong-baker FACES pain rating scale*. Retrieved from <https://wongbakerfaces.org>

### **BIOGRAPHICAL MATERIAL**

Marta graduated from Calvin University with a Bachelor of Science in Nursing degree in 2015. Following graduation, she worked at Bronson Methodist Hospital in adult medicine prior to moving to Indiana. After gaining experience through the float pool at Saint Joseph Regional Medical Center, she began pursuing her DNP at Valparaiso University. Throughout her time in school she has transitioned to follow one of her passions in women's health by becoming a maternal child float, which includes a special focus on postpartum, pediatrics, and neonatal care. Marta is a member of several nursing organizations which include Sigma Theta Tau International, AANP, and CAPNI. Her DNP project was selected for the CAPNI Conference in February where she presented her poster. Her project focuses on pain relief, an area of study that she has pursued throughout the program, as she specifically chose to follow palliative care for specialty clinical hours. Her devotion for palliative and hospice care has grown over the years after experiencing these services through the life and death of several close family members. These specialty areas are one of many interests that she plans to consider after completion of her DNP. During her undergraduate and graduate schooling, she has had several opportunities to travel on medical missions to Honduras and take nursing classes abroad in Belize and Thailand. Marta has a passion for serving others around the world and plans to pursue more medical missions in the future.

**ACRONYM LIST**

CDC: Centers for Disease Control

DNP: Doctor of Nursing Practice

EBP: Evidence Based Practice

EMR: Electronic Medical Record

FLACC: The Face Legs Activity Cry Consolability Scale

IRB: Institutional Review Board

IV: Intravenous

JB: Joanna Briggs Institute

JHNEBP: Johns Hopkins Nursing Evidence Based Practice

JHNEBPM: Johns Hopkins Nursing Evidence Based Practice Model

NP: Nurse Practitioner

VAS: Visual Analog Scale

## Appendix A



## Appendix B

**Authorization & Consent for Use of Buzzy® Device****Patient Name:** \_\_\_\_\_**Birthdate:** \_\_\_\_\_

**Project Title:** What's all the Buzzy® About? Using Cryotherapy and Vibration to Decrease Pain During Vaccinations in the Pediatric Population

**Project Manager:** Marta Byma, BSN, RN, DNP Student Valparaiso University College of Nursing and Health Professions

**Purpose:** This is a consent form for evidence-based practice participation. It contains important information about the project and what to expect if you (as the guardian) decide that your child may participate. Your child is being asked to join an evidence-based practice project for patients receiving a vaccination(s) that will help examine the effects of the Buzzy® device on pain during the procedure.

**Voluntary Participation/Withdrawal:** Your child's participation is voluntary. Please read and consider the information carefully. You may ask questions before making any decision regarding participation and at any time during and after the project's implementation. If you decide that your child may participate, then you will be asked to indicate your child's consent for participation with your (guardian) signature. Your child is allowed to leave the project at any time. There will be no penalty if you or your child makes the decision to be removed from the project. Your decision will not affect any relationship nor the care that is provided in the future at B\*\*\*\*\* Family Medicine.

**Procedure:** If your child participates in this project, the child will be utilizing the Buzzy® device to decrease pain during vaccination. The child will be allowed to hold, touch, and play with the Buzzy® device prior to use during the procedure. Prior to injection, the Buzzy® icepack wings will be removed from the freezer to allow for a couple of minutes to warm before placing directly on the skin. The Buzzy® device will then be placed on the child's injection location for 30 seconds prior to injection. This will cause the area to be slightly numbed prior to injection. During the vaccination procedure, the Buzzy® device will be placed just above the injection site. The vibration and icepack will still be operating, allowing for distraction from the procedure. Following the vaccination process, the medical staff will measure the amount of pain that is reported. If your child is over three years old, the child will be asked to rate their pain on a FACES scale from 0 to 10. If your child is younger than three, then the staff will observe for pain using the FLACC scale, which means looking closely at their face, legs, arms, if they are crying, and how easily comforted they are after the procedure.

**Duration:** If decided that your child will participate in this project, the duration is only one appointment time for vaccination. This is the only time that contact with the patient will occur, no follow-up is necessary.

**Risk:** The potential risk to participating in this project are minimal but can include side effects of skin contact with the coldness of an icepack. Additional safety concerns include discomfort associated with the vibration mechanism of the Buzzy® device.

**Benefits:** The benefits of participating in this project include receiving care based on recommendations from evidence based practice that focuses on improving patient experience and pain relief. This project seeks to improve quality of care and improve patient satisfaction in all aspects of care. An additional goal, is to improve compliance with care and for your child to not fear a visit to the doctor's office.

**Confidentiality:** As the guardian, you understand that the all efforts will be made to keep project-related information confidential. However, there may situations where this information must be released, for example if information is released for state law purposes. In the event that there is any indication of self-harm or harm of others, it will be necessary to break confidentiality for your child's safety and the safety of others. Any information that contains your child's identification information will be only accessible via electronic medical records. General information obtained from this project may be utilized in nursing journals, presentations, or other publications, but no one will be able to identify your child's information as no patient identifiers will be released.

**Contacts and Questions:** For questions and concerns about the project. You may contact the project manager, Marta Byma, at (269) 203-5276 or [marta.byma@valpo.edu](mailto:marta.byma@valpo.edu). You may also contact D. B\*\*\*\*\*, with questions at his office (574) 848-4039. Christina Cavinder, the projects faculty advisor, may be contacted at (219) 548-7797 or [christina.cavinder@valpo.edu](mailto:christina.cavinder@valpo.edu). You may also contact Jennifer Winqvist, Chair of the Institutional Review Board at Valparaiso Univeristy at (219) 464-6841 or [jennifer.winqvist@valpo.edu](mailto:jennifer.winqvist@valpo.edu) if you have questions or concerns regarding the conduction of the evidence-based practice project.

**Consent to Participate:** As the child's guardian, you have read (or someone has read to you) this form, and you are aware that your child is being asked to participate in an evidence-based practice project. You have had the opportunity to ask questions and have had them answered to your satisfaction. You are voluntarily agreeing for your child's participation in this project. You understand the information that has been presented to you. By signing and submitting this form, you are agreeing to your child's participation in this project. A copy of this form will be offered for your records.

**Legal Guardian Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_



## Appendix C



**Goshen Hospital**  
200 High Park Avenue  
Goshen, IN 46526

FWA Number 0000079  
IRB Number IRB00000806  
IORG Number IORG0000484

DATE: August 2, 2019

TO: Marta Byma  
FROM: Goshen Hospital Institutional Review Board

PROJECT TITLE: [1471425-1] DNP Project Proposal for Buzzy Study  
REFERENCE #:   
SUBMISSION TYPE: New Project

ACTION: DETERMINATION OF EXEMPT STATUS  
DECISION DATE: August 2, 2019

REVIEW CATEGORY: Exemption category

Thank you for your submission of materials for this project. The Goshen Hospital Institutional Review Board has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations.

We will retain a copy of this correspondence within our records.

If you have any questions, please contact Debra Filley at 574-364-2476 or [dfilley@goshenhealth.com](mailto:dfilley@goshenhealth.com). Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Goshen Hospital Institutional Review Board's records.